

ACKNOWLEDGEMENT

My heartly thanks to our Principal and H.O.D. Medicine **Prof. Dr.A. M. ABDUL KADAR MD(s)** for his guidance and help to complete this thesis successfully.

My cordial thanks to **Dr.M.ALLIMUTHU MD(s)** Reader. and H.O.D. **Gunapadam** Department for his guidance, timely assistance. Supervision and contribution presenting this dissertation.

My cordial thanks to **Dr.V.BANUMATHI M.D(s)** For her guidance and contribution presenting this dissertation

My Special thanks to **Dr.P.KUMAR MD(s)** **Dr.K.PITCHAYAKUMAR MD(s)** for their guidance and help to complete this thesis successfully

I am also thankful to **Dr.Prof. M. KUMARESAN M.S.DLO (ENT)** who helped for my study.

I extend my cordial thanks to **Dr.SHARAD D.POWER** pharmacology Department CRI Chennai who helped for my work.

I also record my thanks to **Dr.A.GANESAN MD(s), Dr. BOOMINATHAN MD(s)** Who have offered valuable suggestion and help to my work.

My heartly thanks to **Dr.VENKATRAMAN B.PHARM. P.hd.** Director **C.L.BAID METHA** College of Pharmacy Thoraipakkam. Chennai. and **S.V. THIRUNAVUKARASU M.sc.M.Phill** for their guidance and help to complete this study successfully.

My thanks to our librarian **Mr.DHANDAPANI M.Com, M.Lis**

Finally I render this work to my parents.

INTRODUCTION

The WHO [world health organization] document that the vast majority of people (75 – 80%) living in the developing world and industrialized nation prefer to traditional remedies for common ailments and chronic disease. Due to the light cost of modern Hospitalization and expensive drugs and toxic with iatrogenic factors.

Siddha system of medicine is a holistic medicine to treated the individual as a whole and not the isolated case of the disease as found in modern medical science

Siddha medical science give importance to individual body constitution and customize the treatment based on humoral [MUKKUTRAM] pancha potha concepts.

The Vaidhyam (Treatment) is also based upon five Properties of the drugs as suvai (Taste), Gunam (Character) Veeriyam (potency) Private class Mahimai (Action)

The plant kingdom has several thousands of species. Siddhar's have Identified certain plants to posses medicinal properties and named as **Mooligaikal.**

Nilavembu is one among them to cure more diseases especially - NEER PENISAM(Allergic Rhinitis)

Neer Peenisam strongly correlated with allergic rhinitis for its resemble of signs and symptoms approximately 2-6% of Indian population are prevalent for this disease in which Bronchial asthma seen in 50% cases. Pharyngitis, otitis media and deafness are as a result of sino nasal pathology. There is a need for holistic medicine of Indigenes origin. Which has to be effective non-toxic affordable. Especially for those who suffering from allergic Rhinitis.

This dissertation along with siddha perspective. Modern medical science have also been included to evaluate the efficacy of **Nilavembu Chooranam** to alleviate the disease Neer peenisam.

AIM AND OBJECTIVES

AIM

To evaluate the efficacy of **Nilavembu Chooranam** (Powder of Andrographis- paniculata) in the management of Neer peenisam.

OBJECTIVES:

A Systematic study to assess the efficacy of **Nilavembu Chooranam** was aimed and the main objectives of the study are :

- To study the pharmacognostic features of the **Nilavembu** (Andrographis- paniculata) which include correct taxonomic identification of the plant macro and microscopical details of the part used as medicine.
- To subject the Drug to physio –chemical Standardization.
- To Identify the phyto chemicals present in NVC
- To Subject the total drug to thin layer chromatography to determined. The RF Values.
- To study the NVC to bio chemical analysis
- To study the acute toxicity of NVS for fixation of Therapeutic dosage.
- To Study the Pharmacological activity of NVC.
- To ascertain the clinical efficacy of the drug
- MAPA - 2000 – 06 3342 V 22 Page 694.

REVIEW OF LETERATURE

I. GUNAPADAM ASPECT

epyNtk;G

Botanical Name : Andrographis Paniculata (Burm. F) wall.ex.nees

NtWngah;fs; : rpul;Fr;rp> fhz;lfk;> fpuhjfk;> fphpahj;J>
fpuhfjp ehl;LepyNtk;G> mdhjphpajpj;jk;
fLepk;gk; fhz;lk;> Nfhfzk; nfhw;wpiy
Nfhfejk; jpj;jk; Gepk;gk;. G+kpehafd;.

,J xU rpW nrb> epyNtk;ghdJ 1½ mb ePskhfTk; ehd;F %iyfs;
cs;sjhfTk; nfHQ;rk; fWg;ghfTk; ,Uf;Fk;.

gad;gLk; cWg;G : ,iy> jz;L.

Fzk;

Rit : ifg;G

jd;ik : ntg;gk;

gphpT : fhh;g;G

tPhpak; : ntg;gk;.

nra;iffs; :-

grpj;jPj;J}z;b : Stomachic

cukhf;fp : Tonic

clw;Nwe;jp : Alterative
ntg;gKz;lhf;fp : Stimulant

nghJ Fzk; :-

thj Ruk; ePNuw;wk; khw;Wr; RuNjhNI
fhjnkD Xlf; fbAq;fhz; - khjuNr!
gpj;j kaf;fDf;Fk; gpd;G njsp itf;nfhLf;Fk;
Rj;j epy Ntk;gpd; njhopy;.

(mfj;jpah; FzthRIk;)

,jdhy; tspRuk; ePh;f;Nfhit, Ruq;fs;, kaf;fk; ,itfs; ePq;Fk; Gj;jpf;Fj;
njspTz;lhf;Fk;.

tof;F Kiwfs; :-

- epyNtk;G 15 fpuhk; nte;ePhpy; Nrh;j;J %b xU kzp Neuk;
nrd;w gp;d; tbfl;b jpdK; 15 -30 k; yp msT 2-3 Kiw nfhLf;f
ePhNfhit tsp Ruk; Ruq;fs; Nghd;w Neha;fSf;F
nfhLf;fyhk;
- ,jd; ,iy;rhw;iwf; Foe;ijfl;Fz;lhf;Fk; tapw;Wg; nghUkYf;Fk; ,
fopr;rYf;Fk; toq;fyhk;.

epyNtk;G FbePh;

- | | | |
|-------------------|---|-------------------|
| 1. epyNtk;Gr;r%k; | } | FbePh; |
| 2. ntl;b Nth; | | 30-60kpyp fpahok; |
| 3. tpyhkpr;rNth; | | fhiy khiy |

4. re;jdj; J}s; ,UNtis
5. Nga;g;Gly; r%yk;
6. Nfhiuf; fpoq;F
7. Rf;F
8. kpsF
9. gw;glhfk;.

epyNtk;G NrUk; gpwkUe;Jfs; jPUk; Neha;fs;

1. FLr; ahjp f\hak; - Fsph; Ruk;
2. epyw;Fkpo; vz;nza; - cs khe;ij
3. th]hjp f\hak; - Fsph; Ruk;
4. Fl[hjp f\hak; - Ruk;
5. rpW gQ;r %yf; f\hak; - rpj;j gpuk;k rd;jp
6. Nfh\;lhjp f\hak; - fhrk;
7. g+epk;; ghjp #uzk; - tprf;fha;r;ry;
8. gpUfj; fpuhj ijyk; - tprf;fha;r;ry;
9. rpw;w Kl;b FbePh; - tspKg;gpzp Ruk;
10. fPh;guhj;JNt FbePh; - Fsph; Ruk;

BOTANICAL ASPECTS

ANDROGRAPHIS PANICULATA (BURM –F) WALL EX NEES .

SYN: JUSTICIA PANICULATA- BURM.F

TAXONOMY

KINGDOM	-	PLANT KINGDOM.
DIVISION	-	ANGLOSPERM
CLASS	-	DICOTYLEDONE.
SUBCLASS	-	GAMOPETALAE.
SERIES	-	BICARPELLATAE.
ORDER	-	PERSONALES.
TRIBE	-	JUSTICIEAE.
FAMILY	-	ACANTHACEAE.
GENUS	-	ANDROGRAPHIS.
SPECIES	-	PANICULATA.

VERNACULAR NAMES

HINDI	-	KIRYAT, CHARAYETAH, MAHATITA
BENG	-	KALMEGH, MAHATITA
GUJ	-	KIRYATA, OLIKIRYATO, KARIYATU

KAN	-	NELA- BEVINAGIDA, KREATA, NELABERU
MAL	-	NELA- VEMBU, SHIRAT KUCHCHI
TEL	-	NELA VENNU
ARAB	-	OASABUZZARIAH, QASABHUVA
ORIYA	-	BHUINIMBA
PERS	-	NAINE HAVAND
SING	-	NIN-BIN KOHOMBA

ANDROGRAPHIS PANICULATA

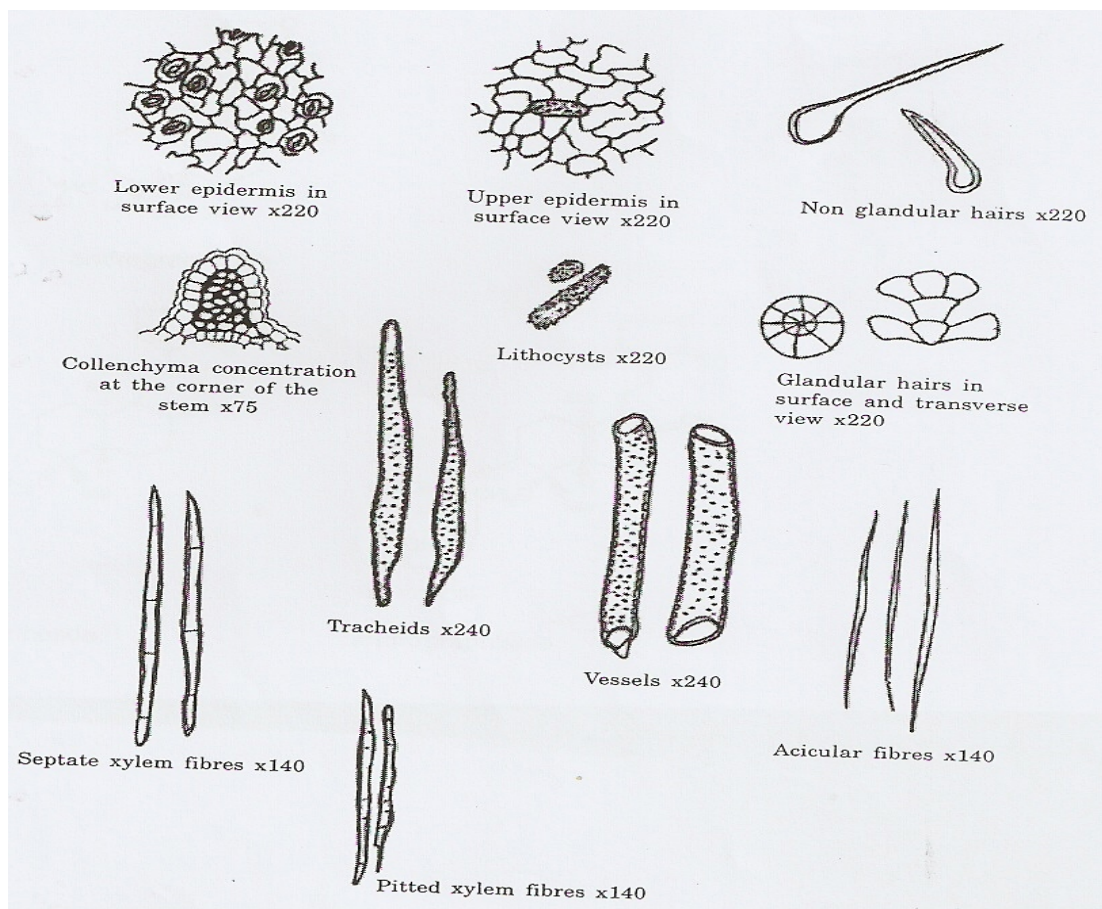
PHARMACOGNOSY

Macroscopic

An erect glabrous, Annual , much branched herb up to 90 cm high, branched sharply quadrangular. Often narrowly winged in the upper part. Leaves simple opposite, short – petiole, 2-7 cm long and 1-3 cm wide, lance late, glabrous, slightly undulate, pale beneath base tapering, main nerves 4-6 pairs, slender; petioles 0-6 mm long . Flowers pink on solitary , auxiliary and terminal panicles. Capsules erect, linear – oblong, compressed, longitudinally furrowed on the broad faces, thinly glandular hairy; seeds numerous, sub-quadrangle.

Leaf

Both the upper and lower epidermii show the presence of glandular trichomes. Lithocysts fairly large on upper epidermis as compared to the lower. Lower epidermis has a layer of wavy walled cells and diacytic type of stomata, which is absent on the upper surface.



STEM

Epidermis has glandular and non-glandular trichomes. Collenchyma densely found at the corners of the stem. Secondary phloem consists of acicular fibre mainly. Xylem fibre are elongated and thickened. Vessels with scalariform and spiral thickenings. Parenchyma cells of the pith contain small acicular crystals of calcium oxalate.

CHEMICAL CONSTITUENTS

Andrographolide, a furanoid diterpene (leaves, root, whole plant); 2'-5-dihydroxy 7,8- dimethoxy flavone 2'-O beta (D)- glucoside, 3-B-hydroxy -5 stigmasta 9 (11) , 22(23)-diene, andrographin, glycoside-neoandrographolide, flavone -5 hydroxy – 7,8,2',3'-tetramethoxyflavone, 5-hydroxy- 7,8 flavanone,

a-sitosterol, apigenin, Mono-oxymethyl- wightin, 5 hydroxy 7,8 dimethoxy dimethoxy flavone, 5-hydroxy 3,7,8,2 tetramethoxy flavone 7-O methylwogonin, apigenin – 7-4' – di-O-methyl ether flavone glucosides, Andrographidines, A,B,C,D,E & F (root); -B-sitosterol glucoside, bitter substances, deoxyandrographolide – 19-B glucoside, neoandrographolide, caffeic chlorogenic, dicaffeoylquinic acids, paniculide, myristic acid, carvacrol, eugenol, hentriacontane, tritriacontane, andrographone, homoandrographolide, a-b unsaturated lactone (leaves), andrographanin.

ADULTERANTS / SUBSTITUTES

The drug is often substituted for or mixed with the genuine 'Chirata' [Swertia chirayita] (Roxb. Ex. Fleming) Karst.] but can be distinguished from the latter easily by the green colour of its stem, numerous erect, slender, opposite branched and its lanceolate green leaves. Kalmegh is also adulterated with Andrographis echinoides Nees. Found in tropical India and in dry districts of Maharashtra, Rajasthan, and Tamil Nadu. However, both Swertia chirayita and Andrographis echinoides are devoid of andrographolide, the major bioactive constituent of Kalmegh.

SAFETY ASPECTS

Gastric discomfort, vomiting and loss of appetite may be caused by the large oral doses of the drug. Injection of the crude drug extract may lead to anaphylactic shock.

PHARMACOLOGY:

Andrographolide and related diterpenes are hepatoprotective agents. These compounds also possess choleric, antidiarrhoeal, immunostimulant, bitter tonic, febrifuge and anti-inflammatory activities.

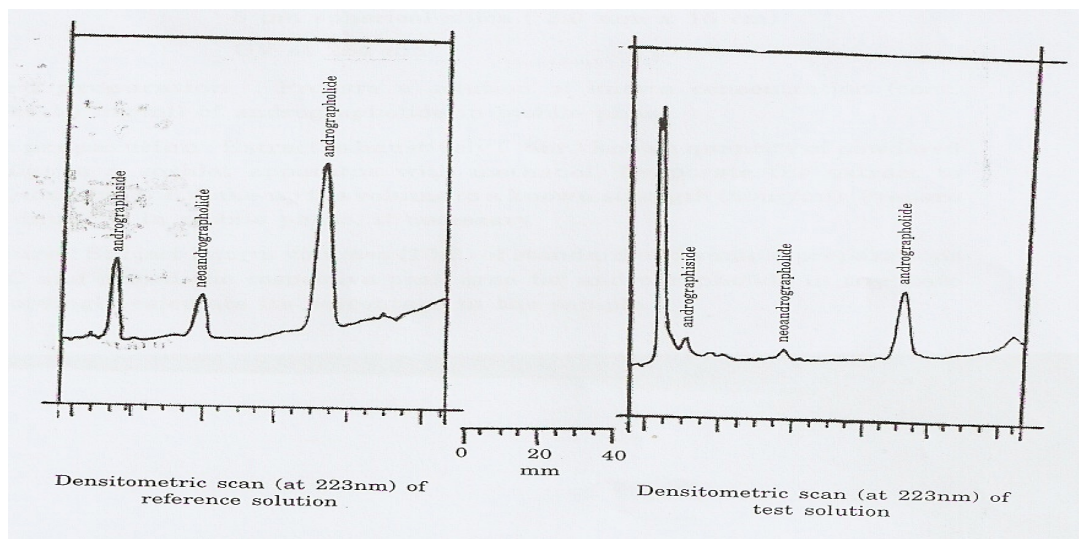
TLC IDENTITY TEST

Test solution : Extract 5g of powdered drug with methanol (50ml) in a soxhlet apparatus (6hr). Evaporate the methanol extract under reduced pressure. Dissolve 10mg of residue in 1 ml methanol.

Reference solution: Prepare a solution containing 1mg each of andrographolide, neoandrographolide and andrographiside in 1.5. ml methanol.

Solvent System: Chloroform : Methanol (7:1)

Procedure: Apply 5 µl each of test solution and reference solution on two different tracks on a precoated silica gel 60 plate (5x20 cms) of uniform thickness (0.2 mm). Develop the plate in the solvent system to a distance of 15 cm



Scanning: scan densitometrically at 223 nm both reference and test solution tracks and record the fingerprint profiles. Quantitation of andrographolide, neoandrographolide and andrographiside in the test solution can be done by comparing their peak areas with those present in the reference solution track.

Visualization of spots (post scanning) : spray the plate with 20% sulfuric acid in methanol and heat at 120° C for 10 min.

Evaluation : in day light: Three different spots visible in reference solution: andrographolide (Rf 0.70, brown) ,neoandrographolide (Rf 0.39, pink) and andrographiside (rf 0.12, Violet) and their corresponding spots in test solution. Other visible spots in the test solution include a light violet spot (Rf. 0.23), a light brown spot just below the spot corresponding to andrographiside , and an unmoved dark green spot at the base.

ASSAY / ANALYTICAL METHOD

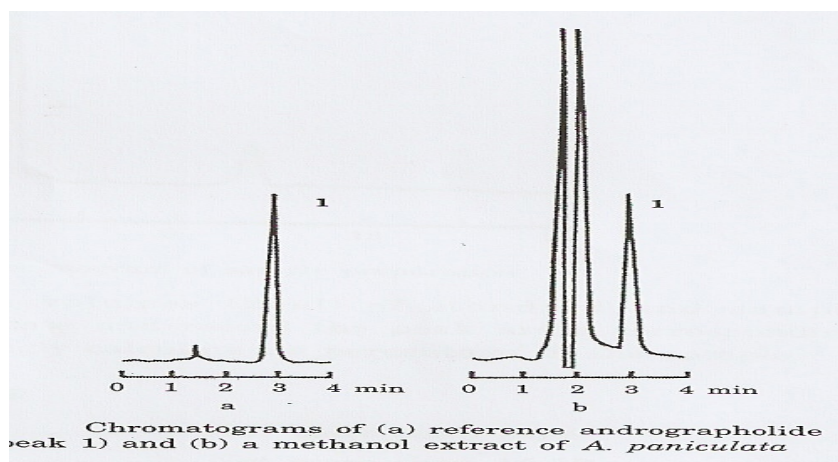
HPLC Analysis of andrographolide – the major bio- active constituent

Mobile phase : Chloroform : Methanol (9:1)
Flow rate : 0.7 ml / min
Column : 5 μ m spherical silica (3.0 mm x 15 cm)
Detector : UV at 254 nm

Standard Preparation : Prepare a solution of known concentration (conc. Rang: 05-10 mg/ml) of andrographolide in mobile phase.

Sample Preparation : Extract exhaustively – (5hr) known quantity of powdered drug (10g) in a soxhlet apparatus with methanol. Evaporate the Extract to dryness, dissolve and make-up the volume to a known strength (50 μ g/ml). Prepare further dilutions in mobile phase, if necessary.

Procedure: subject know volumes (10 μ l) of standard and sample preparations to HPCL and record the respective peak area for andrographolide in triplicate and accordingly calculate its percentage in the sample.



QUANTITATIVE STANDARDATION

Foreign organic matter	:	Not more than 2.0%
Ash	:	Not more than 15.0%
Acid insoluble ash	:	Not more than 3.0%
Alcohol soluble extractive	:	Not more than 8.0%
Alcohol (60%) soluble extractive	:	Not more than 24.0%
Water soluble Extractive	:	Not more than 20.0%

THERAPEUTIC EVALUATION

1. A double blind study with a new mono drug. KAN JAN(Andrographis Paniculata) in a dose of 1200 mg/day has been reported to significantly shorter the course and duration of the disease and is indicated for an enhanced residence to **common- cold**.

MAPA- 9604 – 2072. V18- 4 1996 Page 383.

2. Oral administration of Andrographolide isolated from. A.Paniculata Leaves. Andrographolide. Showed significant (P value Less than 0.05) **analgesic activity** in acetic acid induced writhing in mice.

Andrographolide (100 and 300mg 1 kg oral) produced significant (P less than 0.05) **Anti pyretic** effect. After 3 hrs of administration in. Brewers – yeast induced pyrexia in rats.

Andrographolide also exhibited significant (P Less than 0.05) anti ulcerogenic- activity at 100 and 300 mg/kg doses aspirin induced ulceration in rats. Pharmaceuticals science v-57(3) Pare 121-125-1995

3. Andrographolide a diterpene Lactone isolated from the A.Paniculata after oral administration at doses of 30, 100 and 300 mg 1 kg. significantly inhibited carrageenin induced paw edema the anti-inflammatory activity of andrographolide decreased edema in adjuvant induced arthritis.

Fitoterapia v . 67(5) Page 452 – 458 1996 (Eng 14 Ref)

4. The A.Paniculata drug might have the cell membrane. Stability property which may lead to prevention of the toxic effect of bile salts in various hepatic disorders.

MAPA- 2062 03 – 1662 v. 24 page 392.

5. Antimicrobial activity in vitro and filarial effect of *A.Paniculata* Species against adult worm of sub *Bragia* Malayi.
MAPA -2002 03-17-07 v.24 page 400.
6. The History of using plant based herbal drugs in India is about . 7000 years old using herbal. drugs (*A.Paniculata*) as effective as synthetic drugs for quick relief and permanent cure of in curable disease.
MAPA- 2002 – 04 2118 volume-24 page 506
7. *A.Paniculata* commonly known as king of bitter – which has large importance to the mankind for its therapeutic and much other potential .
MAPA - 2004 – 05 – 2322 volume-26 page 538.
8. Aqueous extract showed significant anti microbial activity which may be due the combined effect of the isolated Arabinogalactin proteins and Andrographolide.
MAPA- 2004. 20839 V.26 – Page 187
9. The data found in the Spontaneous reporting scheme of WHO and Natural drug safety bodies, the data suggested that *A.Paniculata* is superior to placebo in alleviating the subjective symptoms of uncomplicated URI. There is also preliminary evidence of a preventative effect.
MAPA- 2004 - 1610 Volume- 26; Page 378.
10. A Phase of one trial of Andrographolide in HIV-1 Patients and Normal Volunteers leading to rise in CD4 Lymphocyte Level in HIV infected individuals.

Review and literature

ePh;g;gPdprk;

NtW ngah;fs;

gPdprk; > ePh;f;Nfhit ,%f;FePh;gha;jy;

,ay; :-

%f;fpd; Jisfs; rpte;J> Jk;ky; fz; rpte;J ePh;tbyj; ,%f;fpy;
ePhgha;jy;, jiy Nehjy; mbfb %f;if rpe;jp ePh; tUjy; vd ,ay;GilaJ.

%f;fpy; cz;lhf; Neha;fs; 86 ,tw;wpy; gPdpj;jpd; fPo; 9
tifahf tifgLj;jp ePh; gPd;rk; xd;whf tifg;gLj;jgl;Ls;sJ

Neha; tuf;fhuzq;fs;:-

1. kpfTk; Fsph;e;j ePiu gUFjy;
2. gdp my;yJ Fsph;e;j fhw;wpy; <Lgly;
3. G*jp \$ba fhw;W Jk;kiy cz;lhf;f \$ba nghUs;fis Kfh;tjhYk;
4. laj;ij ngUf;f \$ba Fsph;e;j ePhpy; jiy %o;Fjy;
5. Fsph;r;rp jUk; nghUs;fis cl;nfhs;Sjy;
6. gjpdhW Ntfq;fis rhh;e;j fz;zPh; the;jp ,tw;iw mlf;FtjhYk;
7. msTf;F kpUe;jhtJ Fiwe;jhtJ J}f;fk; nfhs;tjhYk; gPdpr
Neha; Vw;gLk;.
8. xt;th kz%;L nghUl;fs; Ef;h;jy;.

gpdprj;jpd; nghJ Fzq;fs;:-

“jiypkf typf;Fk; ehrp rsptpo nkhLTz;lhfK;
eypWT Jk;kYz;lhfK; ehl;nrypy; twS ehrp
kiyTwj; jpuz;L tpOk; thANk ehw;wKz;lhk;
ngy Kw %f;filf;Fk; gPspr nkd;Nw NjNu”

ePh; gPdprj;jpd; Fzk;:->

“fz;lNkd; Kfq;fz; fhJ fufuj; J}h;t NjNghy;
Jz;l Nkd; wpdT gw;wpr; nrhhpe;J}jd; ryKk; tPo;e;J
kz;ilAq; fdj;J nehe;J typkpf TsNj ahfpy;
gz;LNrh; %f;fpdphpg; gha;r;rhyd; Wiuf;f yhNk”

%f;fpd; ntspGwj;jpy; ePh; Xbf;nfhz;bUg;gpd; mjid
Kz;zPh;g;gha;r;rnydTk; (Rhinorrhoea) njhz;ilapDk; Gwj;Nj ePh;
ngFjp thapd; top th;d gpd; ePh; gha;r;rnydTk; \$Wth; (Post Nasal
Drip)

FwpFzq;fs; :-

1. %f;filg;G Nasal blook
2. %f;fpy; ePh; gha;jy; (Rhinorrhoea)
3. %f;FePh; njspthf fhzg;gly; (Watery discharge)
4. jiy Neha;; (Headache)
5. Ruk; (Feverish)
6. cly; Nrhk;gy; (Malise)
7. if fhy; Nehjy; (Body Pain)

Kf;Fw;wk; :-

czT Kjypa nray;fshy; cly; ntg;gkile;J moy; Fw;wk; kpFe;J
NghJ [ae;ijg; ngUff;\$ba nray;fshy; gpwe;j [ak; moNyhL
\$bg;gpwe;j NehahUk;

ehb:-

gz;ghz gpj;jj;jpy; Nrj;Jkk; \$b

ghprpj;jhy; gPdprKk;.

rjf ehb

MATERIALS AND METHODS

PREPARATION OF THE NILAVEMBU CHOORANAM

The Drug “Nilavembu” was taken from the ‘Agastiyar Gunavagadam’ found in Siddha text book Gunapadam mooligai (siddha Mederia Medica Medicinal plants division) written by Dr. Murugesu mudaliyar .

COLLECTION OF THE TEST DRUG

Nilavembu- [Andrographis Paniculata] Plants were collected from agricultural land at Vandavasi Tiruvannamalai District. The identity was conformed by Dr.SasikalaEthirajalu Botanist CRI for siddha Chennai 600 106. with the help of pharmacognostic study.

PROCEDURE :-

The Fresh plants were washed well in the running water to remove the impurities then the plants were cut into pieces and dried in shade. After drying they were finely powdered to obtain the medicine in its finest physical form the powder is sieved through a white cloth. [VASTHARAKAYAM]

PURIFICATION OF THE CHOORANAM

The powder was moistened with cow's milk . The pot was half filled with milk and water the mouth of the pot was covered and tied with while cotton cloth the chooranam (moistened by milk) was placed above. The tied cloth the mouth of the pot closed with another mud pot. The gap between the two mud pots was tied with a wet cloth to avoid evaporation, then this arrangement was put on fire and boiled until water level gets reduced in the lower pot, then the powder was taken dried powdered finally and preserved for usage.

STORAGE OF THE CHOORANAM

The chooranam was stored in a clean air tight glass container . The life period of the chooranam is three month the prepared chooranam was used within the period.

ADMINISTRATION OF THE DRUG

FORM OF THE MEDICINE	ROUTE	DOSE	TIME OF ADMINISTRATIVE	VEHICLE
Chooranam	Enternal	1 g two times/day	After food	Hot water {about 30 ml}

The prepared **Nilavembu chooranam** was done subjected to various analyses and the methodology followed is given.

TOXICITY STUDY

1.1 Test Drugs

The following medicinal plants were used in the study were collected and processed by the methods prescribed in standard text books of siddha medicines.

1.1 Nilavembu Chooranam [NVC]

NVC was prepared by the method described in Gunapadam Mooligai-Vaguppu . page no : 579-80)

1.2 Preparation of drug for dosing

All drugs used for the study was suspended each time with 1% (w/v) solution of sodium car boxy methyl cellulose before administration.

1.3 Drugs and chemicals

Histamine hydrochloride and fine chemicals used in these experiments were obtained from Sigma Chemicals company, U.S.A. Other analytical grade chemicals were obtained from S.d. Fine Chemicals Ltd., Mumbai.

1.4 Experimental animals

Colony inbred animals strains of Wister rats of either sex weighing 200 - 250 g were used for the pharmacological and toxicological studies. The animals were kept under standard conditions 12:12 (day/night cycles) at 22⁰C room temperature, in polypropylene cages. The animals were fed on standard palliated diet (Hindustan Lever Pvt Ltd., Bangalore) and tap water *ad libitum*. The animals were housed for one week in polypropylene cages prior to the experiments to acclimatize to laboratory conditions. The experimental protocol was approved by the Institutional Animal Ethical Committee (IAEC).

1.5. Acute oral toxicity study.

Acute oral toxicity was conducted as per the OECD guidelines (Organization of Economic Cooperation and Development) 423 (Acute Toxic Class Method). The acute toxic class method is a stepwise procedure with 3 animals of a single sex per step. Depending on the mortality and /or moribund status of the animals, on the average 2-4 steps may be necessary to allow judgment on the acute toxicity of the test substance. This procedure results in the use of a minimal number of animals while allowing for acceptable data based scientific conclusion.

The method uses defined doses (5, 50, 300, 2000 mg/kg body weight) and the results allow a substance to be ranked and classified according to the Globally Harmonized System (GHS) for the classification of chemicals which cause acute toxicity.

Wistar albino rats of either sex weighing 200-250 g were fasted overnight, but allowed water *ad libitum*. Since the formulation is relatively non toxic in clinical practice the highest dose of 2000 mg/kg/p.o (as per OECD guidelines “Unclassified”) was used in the acute toxicity study.

The animals were observed closely for behavioral toxicity, if any by using FOB (Functional observation battery).

1.6 Repeated oral toxicity study

Repeated oral toxicity studies can be used to get additional information regarding the toxicity profile of a chemical. Repeated oral toxicity studies are defined as those studies where the chemical is administered to the animal for a period covering approximately 10% of the expected life of the animal.

Usually, the dose levels are lower than for acute studies and allow chemicals to accumulate in the body before lethality occurs, if the chemical possess this ability.

1.8 Experimental procedure

The following experimental procedure was followed to evaluate the repeated oral toxicity study of:

Nila Vembu Extract (NVE)

Group I : Control animals received 1% Sodium carboxy methyl cellulose (CMC), 2 ml/kg/p.o. for 21 days

Group II : Drugs suspended in CMC was given at the dose Level of 500 mg/kg/p.o. for 21 days

Body weight, food intake and water intake was recorded at two intervals with simultaneous observation for toxic manifestation and mortality, if any. At the end of 21 days treatment all the animals were sacrificed by over dosage of ether anesthesia. Blood was collected and used for hematological studies. Section of liver, kidney, and heart were dissected out and kept in 10% formalin for histopathological studies.

RESULT

Acute oral toxicity study

NVE at the dose of 2000mg/kg/po did not exhibit any mortality in rats. As per OECD 423 guidelines the dose is said to be “Unclassified” under the toxicity scale. Hence further study with higher doses was not executed.

Repeated oral toxicity for 21 days

Test drug NVE at the dose of 500 mg/kg/po when administered orally for 21 days in rats did not show toxicity in renal functions. There was a significant increase in % of Hb and RBC (Table 2). However the drug did not show any significant elevation of marker enzyme levels of liver (Table 3).

Table 1

Effect of Siddha Formulations (NVE) on Hematological parameters after 15 days repeated oral dosing (500 mg/kg)

Groups	Hb (gm/100ml)	RBC (millions/ cu.mm)	WBC (cells/cu.mm)	Differential leucocyte count (%)		
				Lymphocytes	Mono cytes	Granulo cytes
Normal	13.08 ± 0.34	4.31 ± 0.35	54850 ± 9.44	76.06 ± 3.89	5.30 ± 1.04	16.50 ± 4.27
NVE (500mg/kg/p.o)	13.68 ± 0.70 ^{ns}	4.68 ± 0.72 ^{ns}	5786.66 ± 3.323	77.67 ± 3.32 ^{ns}	8.16 ± 1.7 ^{ns}	16.66 ± 3.44 ^{ns}

n=6; Values are expressed as mean ± S.D followed by Students Paired 'T' Test

ns – non significant when compared to control groups

Table 2

Effect of Siddha formulation (NVE) on Biochemical markers of liver and kidney after 15 days repeated oral dosing (500 mg/kg/po) in rats

Groups	ALP (K.A.Units)	AST (IU/L)	ALT (IU/L)	Urea (mg/100ml)	BUN (mg/ 100ml)
Normal	3.78±0.38	78.48±0.23	28.70 ± 0.81	13.56 ± 0.37	6.48 ± 0.50
NVE (500mg/kg/p.o)	4.32±0.75 ^{ns}	79.55±5.92	30.13 ±	14.60 ± 0.69	7.51 ± 0.35 ^{ns}

		ns	2.67 ^{ns}	ns	
--	--	----	--------------------	----	--

N=6; Values are expressed as mean \pm S.D followed by Students Paired 'T' Test

Ns – non significant when compared to control groups

ANALGESIC ACTIVITY

TAIL FLICK METHOD

Withdrawal of tail (Tail Flick) for noxious thermal (radiant heat) can be used for screening **Neelavembu Chooranam** with analgesic activity. Radiant heat can be generated by passing electrical current through nichrome wire mounted in an analgesiometer.

The base of the tail of the test rats is placed on a nichrome wire. The tail withdrawal for the radiant heat (flicking response) is taken as the end point. Normally the rats and mice withdraw their tails within 3 – 5 secs. A cutoff time of 10 – 12 secs is used to prevent damage to the tail. Any animal failing to withdraw its tail in 3-5 secs is rejected from the study.

The reaction time of test drug, standard and control are taken at intervals of 30, 60 and 120 mts. A reaction time (withdrawal time) increment of 2-5 secs more than the control animals can be considered for analgesic activity of the drug.

Table 3

Analgesic activity of NVE using Tail flick Method

Groups	Paw licking response (Sec)			
	0 min (Sec)	30 min (Sec)	60 min (Sec)	120 min (Sec)
Control	1.56 ± 0.96	1.86 ± 0.96	1.76 ± 0.67	1.86 ± 0.53
Test (500mg/kg. p.o.,)	1.86 ± 0.206 ns	3.133 ± 0.258 ***	4.966 ± 0.516 ***	5.15 ± 1.394 ***

n=6, Values are expressed as mean ± S.D using followed
by student paired T – test , ns- non significance

***P<0.001 as compared with control.

ANTI - INFLAMMATORY ACTIVITY

Anti inflammatory activity was evaluated in acute model of inflammation.

Acute model

Carrageenan induced hind paw edema

The carrageenan assay procedure was carried out according to the method of Wintar *et al.* (1962). Edema was induced by injecting 0.1 ml of 1% solution of carrageenan in saline into the plantar aponeurosis of the left hind paw of the rats. The extracts, reference drug and the control vehicle (distilled water) were administered 60 min prior to the injection of the carrageenan. The volumes of edema of the injected and contra lateral paws were measured at +1, 3 and 5 hrs after induction of inflammation using a plethysmometer (Bhatt *et al.*, 1977) and percentage of anti-inflammatory activity was calculated.

Table 4

Anti inflammatory activity of NVE induced end paw edema in rats

Groups	Paw volume (ml) by mercury Displacement at regular interval of time					
	0min	30min	60min	120min	240min	15 hrs
Control	1.233 ± 0.338	1.733± 0.225	2.066± 0.286	2.200 ± 0.236	2.25 ± 0.273	2.266± 0.236
NVE (500mg/kg. p.o.,)	1.233 ± 0.338 ns	1.40 ± 0.236 ns	2.03 ± 0.2366 ns	1.566± 0.316 ***	1.533 ± 0.372 ***	1.491 ± 0.174 ***
Standard (Dic.Sodium 5 mg/kg/po)	0.835 ± 0.065 ^{ns}	1.315 ± 0.069 ^{ns}	1.128 ± 0.049 ^{***}	1.011 ± 0.056 ^{***}	0.896 ± 0.048 ^{***}	0. 85 ± 0.054 ***

n=6; Values are expressed as mean ± S.D followed by student paired T- test.

ns - Non significant as compared with control;

P< 0.001 (***) as compared with control.

HISTAMINE STUDY

Antagonistic action of PC in Guinea pig ileum contraction.

Histamine is an autocoid having many physiological effects in the system. Histamine has spasmogenic response in g.pig ilium. Histamine by acting on H_1 receptor of smooth muscle causes contraction which can be recorded by a kymograph. Drugs acting as H_1 receptor antagonists, block the contraction of histamine in g.pig ileum.

G.pig ileum is dissected out and placed in the watch glass containing Tyrode solution. Dissect out the ileum and clean the contents of the ileum by pushing the Tyrode solution into the lumen of the ileum.

2 – 3 cm long ileum is taken and mounted to the tissue holder of the organ bath containing Tyrode solution maintained at $32 - 34^{\circ}\text{C}$ and bubbled with a mixture of $\text{CO}_2 + \text{air}$.

A tension of 0.5 g is applied to the lever and the tissue is allowed to equilibrate for 30 mts before adding drugs. Record concentration dependent response ($10\ \mu\text{g} - 80\mu\text{g}$) due to histamine using a frontal writing lever. Add the test drug in different concentrations ($2\ \mu\text{g} - 5\mu\text{g}$) to the tissue bath and repeat the concentration- response curve of histamine in the presence of the test drug. Calculate the % inhibition of contraction by the test drug.

Histamines activity - showed in chymograph

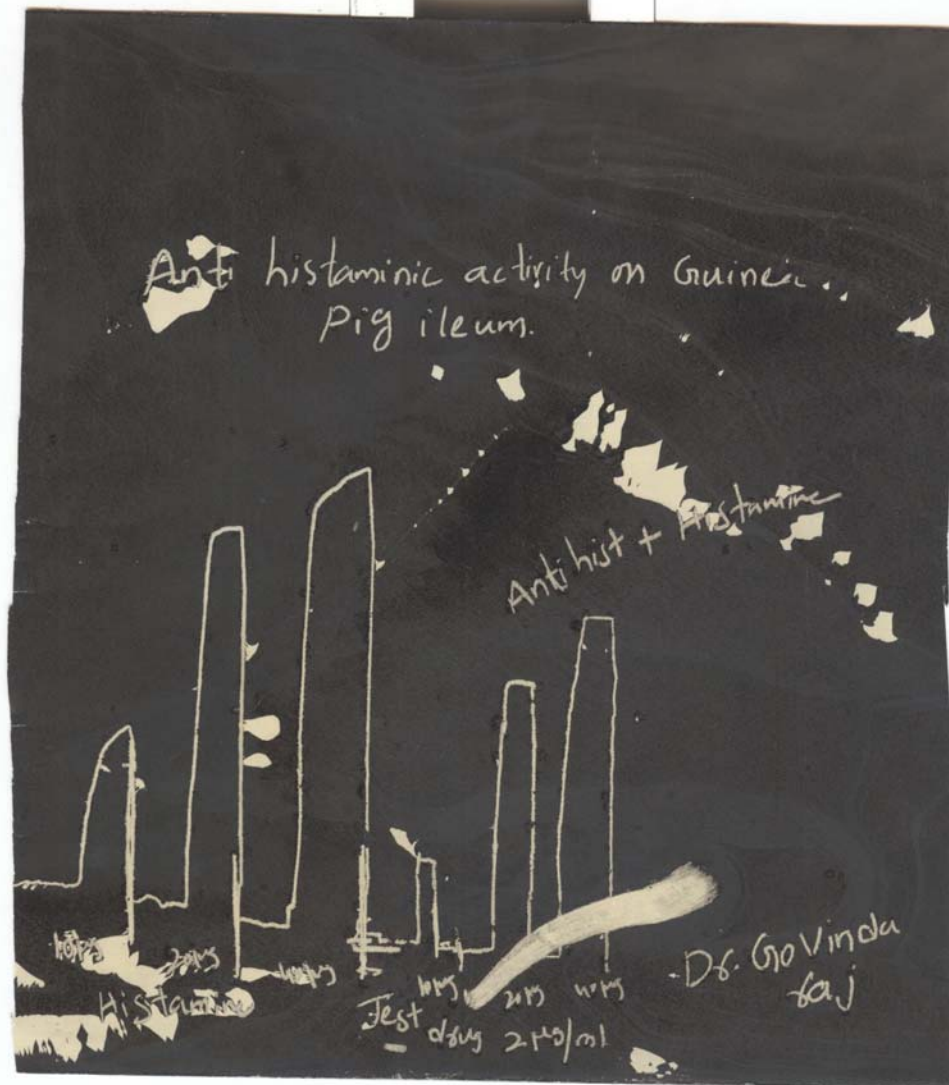


Table 5**Effect of the NVE on histamine induced contractions of guinea pig ileum**

S.No	Treatment				
	Histamine μg/ml	Mean contraction n (M meter)	NVE μg/ml	Mean contraction M meter	% inhibition of Histamine
1.	10.0	25.62 ± 0.322	10.0	10.08 ± 0.147 ***	40.0
2.	20.0	54.0 ± 0.672	20.0	37.33 ± 0.216 ***	68.5
3.	40.0	66.130 ± 0.271	40.0	47.5 ± 3.216 ***	71.5
4.	80.0	75.0 ± 0.546	80.0	54.60 ± 0.967 ***	72.0

n=6; Values are expressed as mean ± S.D followed by Students
Paired 'T' Test

P<0.001 as compared with that of control.

RESULTS

Analgesic, Anti inflammatory and Anti histaminic studies

Nila Vembu Extract (NVE) is used in the Siddha system of medicine for its anti allergic activity. In the present study NVE showed antagonistic action against Histamine induced contractions in guinea pig ileum. Histamine assay in g.pig ileum is used to evaluate the antihistaminic activity of drugs acting on H₁ receptors. NVE showed a dose dependent reduction in the height of contraction for histamine in g.pig ileum. NVE also exhibited antiperoxide and antioxidant activity against oxygen free radicals.

ANTI MICROBIAL STUDY

Paper disc diffusion method

The sterilized (autoclaved at 120 ° C for 30 min) medium (40-50 ° C) was inoculated (1 ml / 100 ml of medium) with the suspension (10^5 cfu mL⁻¹) of the microorganism (matched to Mc Farland barium sulphate standard) and poured in to a petridish to give depth of 3-4 mm. The paper impregnated with the test compounds (25, 50, and 100 µg mL⁻¹ in dimethyl farmamide) was placed on the solidified medium. The plates were pre incubated for 1 h at RT and incubated at 37o C for 24 and 48 h for anti bacterial and anti fungal activities, respectively. Ciprofloxacin (100 µg /10 disc) and ketoconazole (100 µg/ disc) were used as standard for anti bacterial and anti fungal activities, respectively. The observed zone of inhibition is presented in table In-vitro antimicrobial activity of NVE as screened against bacteria and yeast strains. The results are depicted in Table 6. In 10 µl/disc concentration of NVE were exhibited low antibacterial activity in streptococcus mutans and aereus. others were exhibited moderate to high antibacterial activity when compared to standard drugs ciprofloxacin and ketoconazole respectively.

Table 6

Zone of inhibition in mm

Organism	Standard drug Ciprofloxacin 50 mcg/disc	Test drug (NVEµl/disc)		
		Zone of inhibition in mm		
		10µl	25µl	50µl
Strep. Mutans	30	15	19	22
Staph. Aureus	31	13	16	19
E.coli	31	12	18	22
K.pneumoniae	30	11	14	19
Ps.areginosa	31	13	16	19

In vitro anti microble activity of **Nilavembu Chooranam** extract showed that the drug was sensitive to Streptococcus Mutans staphylococcus Aureus and resistant to K. pneumoniae

ANTIOXIDANT STUDY

In Vivo Antioxidant study

Samples of serum collected from rats treated with test drugs were assayed for GSH (Moron *et al* , 1979) and LPO (Yagi, 1976) and the results were compared with control group.

Table 7

**Anti oxidant activity of Siddha Formulation (NVE)
after 15 days repeated oral dosing (500 mg/kg)**

Groups	LPO	GSH
Control	0.63 ± 1.37	46.28 ± 2.31
NVE (500mg/kg/p.o)	0.42 ± 3.90 ^{***}	83.31 ± 0.35 ^{***}

N=6; Values are expressed as mean ± S.D followed by Student T- Test.

^{***}P<0.001 as compared with control.

Antioxidant activity

At the end of 21 days repeated oral toxicity study when the plasma of drug treated animals was examined for GSH activity, the level of GSH activity was increased significantly (p>0.001) in test groups. On the other hand the LPO activity was considerably reduced in drug treated group when compared to control.

QUALITATIVE ANALYSIS OF ACIDIC/BASIC RADICALS AND BIO-CHEMICAL CONSTITUENTS IN TEST DRUGS

Procedure	Observation	inference
Test for Calcium : 2 ml of extract is taken in a clean test tube. To this add 2 ml of 4% ammonium oxide solution.	white precipitate is formed	Presents of calcium
Test for Sulphate : 2 ml of the extract is added to 5 % barium chloride solution.	white precipitate is formed	Presents of Sulphate
Test for Chloride : The extract is treated with Silver nitrate solution	white precipitate is formed	Presents of Chloride
Test for carbonate : The substance is treated with Conc. HCl.	effervescence is formed	Presents of carbonate
Test for Starch : The extract is added with weak iodine solution	Blue colour is formed	Presence of starch
Test for Iron (Ferric) : The extract is treated with glacial acetic acid and potassium ferrocyanide	blue colour is formed	Presents of Ferric iron
Test for Iron (Ferrous) : The extract is treated with Conc. HNO_3 and ammonium thiocyanate	No Blood red colour is formed	Absence of Ferrous iron
Test for phosphate : The extract is treated with ammonium molybdate and conc. HNO_3	Yellow precipitate is formed	Presence of phosphate
Test for Tannic acid : The extract is treated with Ferric chloride	Blue black precipitate is formed	Presence of Tannic acid
Test for Unsaturation : 1 ml of Potassium permanganate solution is added to the extract.	get decolourised	Presents of unsaturated compound
Test for saponins: Dilute extract+ 1ml of distilled water shake well.	No Froth formation	presence of saponins
Test for sugars : Benedict method ; 5ml of Benedict solution heated gently then add 8 drops of diluted extract then heated in a boiling water bath.	No colour change	Indicates the Presents of sugar

Molisch test ; Dilute extract+2 drops of Molisch+3ml conc.H ₂ SO ₄ .	No Reddish violet zones appeared	Absence of carbohydrate
Test for steroids : Liberman Burchard test ; Dilute extract +2 ml acetic anhydride+conc.H ₂ SO ₄ .	Formation of red colour	Presences of steroids
Test for amino acids : Dilute extract +2ml of Ninhydrin's soln .	Formation of violet colour	Presents of amino acids
Test for proteins : Biuret method ; 1ml of dilute extract+1ml of 5% CuSO ₄ + 1% NaOH.	Formation of Violet colour	Presence of proteins
Test for Flavanoids : Dilute extract+ mg bits+2drops of conc.HCl and gently heated.	No formation of pink colour	Absence of Flavanoids
Test for phenol ; Dilute extract+2drops of FeCl ₃ soln.	Deep green colour is formed	Presence of phenols
Test for Tannins ; dilute extract +2ml of 10% lead acetate add.	White precipitate formed	Presence of tannins
Test for alkaloids ; Mayer's method; 1ml of dilute extract + 1ml reagent. Dragendroff's method; 1ml of dilute extract+ 1ml of reagent.	Appearance of cream colour precipitate Appearance of orange colour precipitate	Presence of alkaloids Presence of alkaloids

Result :

From the biochemical analysis the following chemical were. Found to be present in the test drug (NVE)

- **Acid Radicals**

- Sulphate
- Phosphate
- Chloride

- **Basic Radicals**

- Calcium
- Iron
- Potassium
- Magnesium

CLINICAL ASSESSMENT

STUDY DESIGN

1. Open clinical trial
2. Parameters for Evaluation .

SYMPTOMS

- | | |
|------------------------|-------------------------------|
| 1. Thummal | [Sneezing] |
| 2. Mookil Neer Paithal | [Rhinorrhoea] |
| 3. Namaichal | [Itching Nose, Exes Throat] |
| 4. Mokadaippu | [Nasal Block] |
| 5. Thalai vali | [Headache] |

LINE OF TREATMENT

- a. Does 500 mg bid = Hot water
- b. Root of administration. External
- c. Duration : 45 days

SELECTION OF PATIENTS

Sample size – 30 patients 30 patients are selected on the basis of the inclusion and exclusion criteria

Inclusion

1. Signs and symptoms of Neerpenisam
2. Age Between 15 – 60 yrs from age sex

Exclusion

- 1 Acute Phase of BA
2. Patient Who have RVF / CCF
3. Patient Who have any other uncommittant illness
4. Patient With known liver or kidney disorders
5. Patient having hyperpyrexia.

WITHDRAWAL CREITERIA

1. Irregular treatment

To prevent with drawl of study medicine. Was given to each patients for a period of 15 days.

INVESTIGATION

Blood investigation including HB% and TLC (Total Leucocytes Count) Raised Eosin Phil count on differential court suggested allergic with the body 65% had raised Eosin Phil count

X RAY:

Hypertrophied mucous of nose and Para nasal sinuses (PNS) Indicate allergic causes with the nose and PNS..

DIAGNOSIS was based mainly on history of neer peenism symptoms and also by considering the demonstration of allergy on blood investigation and nasal smear or by x-ray investigation statistical analysis of treatment is recorded and tabulated as follows.

Table 8

AGE WISE DISTRIBUTION

S/no	Age in years	No of Patient	Percentage
1	16-25	16	53.4
2	26-35	6	20
3	36-55	8	26.6
	Total	30	100

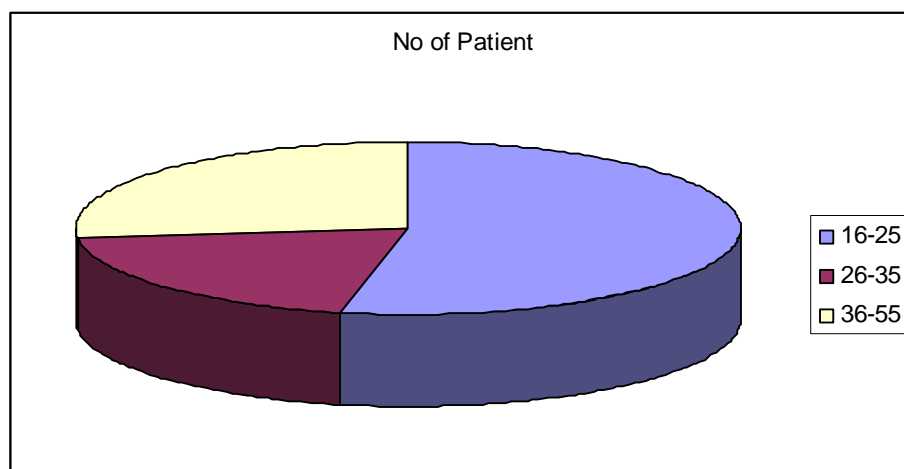


Table 9

SOCIO-ECONOMIC STATUS

S/no	Eco Status	No of Patient	Percentage
1	Poor	8	26.7
2	Middle	21	70
3	Rich	1	3.3
	Total	30	100

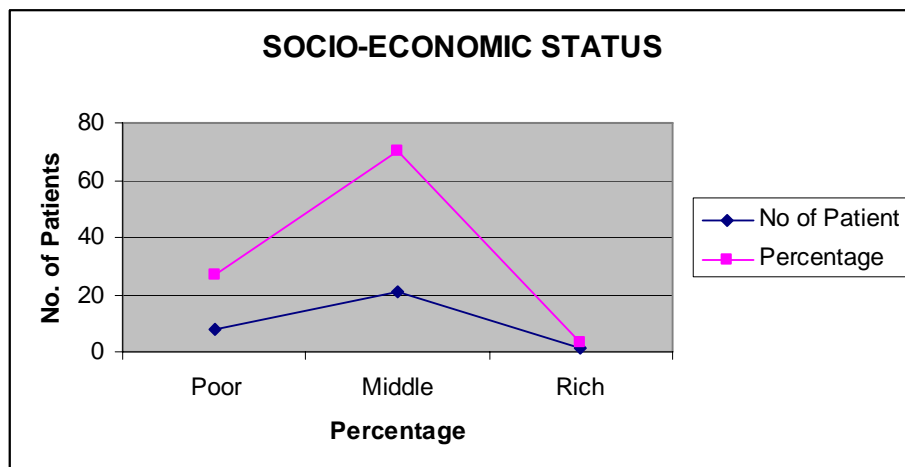


Table 10

DIET

S/no	Diet	No of Patient	Percentage
1	Vegetarian	4	13.4
2	Mixed – diet	26	86.6
	Total	30	100

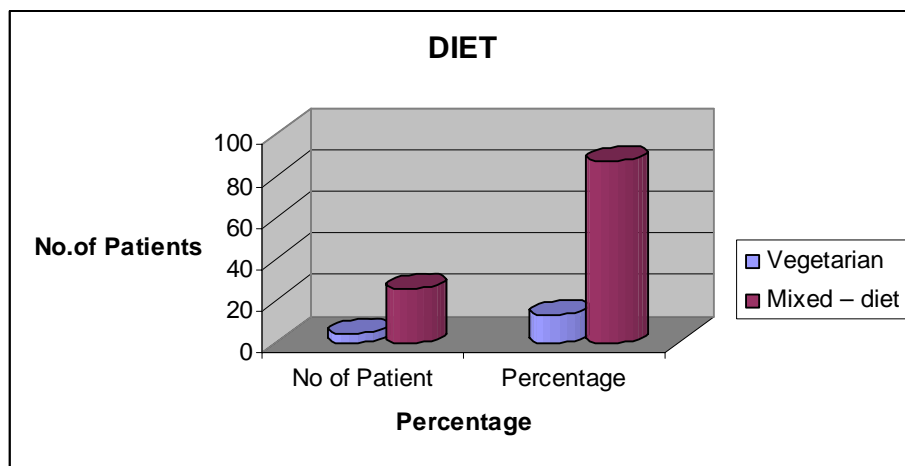


Table 11

OCCUPTION STATUS

S.no	Occupation	No of Patient	Percentage (%)
1.	Daily Labour	10	33.4
2.	House Wife	7	23.4
3.	Office Worker	3	10
4.	Auto Mobile	5	16.6
5.	Sales Rep.	3	10
6.	Students	2	6.6
	Total	30	100

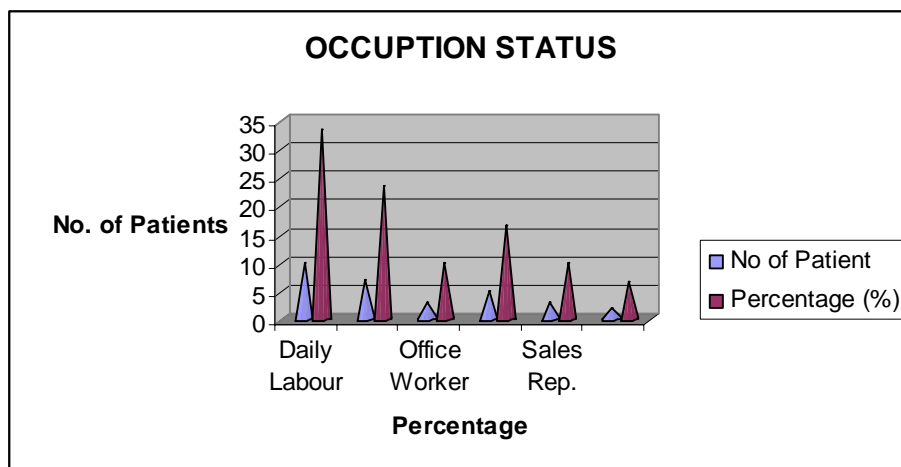


Table 12

**IMPROVEMENT OF SIGNS AND SYMPTOMS
OBSERVED BEFORE AND AFTER
TREATMENT OF 30 (N)
PATIENTS OF NEER PEENISAM GSMC, CHENNAI – 106.**

S.No	Signs And Symptoms	Number Of Patient		Percentage (%)
		Before Treatment	After Treatment	
1	Itching [Nose, eyes, throat]	30	0	100
2	Sneezing	24	1	95.83
3	Rhimorrhoea	30	3	90
4	Nasal block	24	4	83.33

Table 13

**RESULTS OF STATISTICAL ANALYSIS OF
SUBJECTIVE PARAMETERS OBSERVED
BEFORE AND AFTER TREATMENT
OF 30(N) PATIENTS OF NEERPEENISAM GSMC, CHENNAI**

S.no	Parameters	Mean value		Difference Present	Statistical Test criteria	Probability (P) Value	Statistical significance
		Before Treatment	After Treatment				
1.	Itching [Nose, eyes, throat]	30.0± 4.472	0.01± 0.01	NIL	16.432	0.001	Significant
2.	Sneezing	24.0± 5.777	1.0± 0.242	23.0± 0.437	16.432	0.001	Significant
3.	Rhimorrhoea	30.0± 4.472	3.0± 0.342	27.0± 0.572	16.432	0.001	Significant
4.	Nasal block	24.0±	4.0±	20.0±	16.672	0.001	Significant

Values are compared with test one sample student T.test

SUMMARY

In this dissertation **Nilavembu chooranam** (NVC) was taken to evaluate its efficiency on neerpeeniam.

Botanical aspect of the drug **Nilavembu** (*A. paniculata*) was studied regarding its identification description by pharmacognostic study.

In Gunapadam aspect **Nilavembu chooranam** indicated for treating peeniam which is comes under kapha disease so the idea to evaluate the therapeutic efficacy of this drug in Neer penisam patients carried out at Aringnaranna Hospital P.G. Gunapadam Dept. Chennai – 106

Biochemical analysis revealed that the NVC Contains Phosphate, Calcium, Sulphate, Chloride, Iron. The pharmacological analysis showed that the drug has got anti-inflammatory action in albino rats, anti histaminic action in guie pig.

Micro biological studies revealed that the drug posses anti microbial activity against Straps-mutans. In clinical study 30 patients were selected and treated the drug was administered in the form of chooranam at the dose 1 gm twice a day with hot water after relevant diet restriction and medical advice were given to all the patients.

The clinical study showed that the drug NVC is statistically significant in Neer peeniam [allergic rhinitis] and also the symptoms of Sneezing, Nasal discharge, Itching and Nasal obstruction.

DISCUSSION AND CONCLUSION

In siddha system of medicine Neer peenisam is caused by increased thosha like kapham and vatham.

In normal body these doshas are statically distributed in normal. But in neerpeenism Kapha dosha is increased in the body where the neck to head, is ruled by kapha humer. Allergy is the main aggravating factor for this disease. In siddha peosepective pancha boothic and arusavai are vital role while treating the patients with medicine. According to these theories suvai and veeriyam of the drugs acts against the kapha disease.

The bitter taste drugs we given to patients controls kapham and neutralize vatham. The above tast substance have vemai veeriam and first against the increased kabam and normalize the kabam dhosham and neatrolize the vatham.

Histamine plays very important role in the early signs and symptoms of allergy like vasodilatation, smooth muscle contractions and edema formation. The antagonistic action exhibition by NVC for histamine in g.pig ileum shows the H1 - receptor antagonistic activity of NVC also exhibition anti peroxides and anti oxidant activities in the appropriate experimental models.

Nilavambu is widely used in kabha dosha like kabha suram which is mainly caused by kabha humer so the activity of NVC is the drug of choice for neer peenisam.

Pharmalogical study reveled that NVC have Anti Inflammatory, Anti histaminic analgestic activity .

Biochemical analysis the following chemical were found to be present in the NVC.Calcium, iron, magnesium, and phosphate.

Iron transport of oxygen to the use of tissue participation in cellular oxidation-mechanism. Magnesium which help to Keep the mind calm keeps nerves relaxed.

Chloride help in the preservation of the permeability of the cells and normal neuromuscular irritability in the ECF and ICF

On clinical study age distribution between 15 to 60 years patients from either sex various economical status and habitats were taken for this study.

In this study it is noted that, out of 30 patients sharing this signs and symptoms 22 patients have good improvement, 5 patients have moderate improvement and 3 patients shared poor prognosis.

From this study it is revealed that NVC has beneficial effects in Neer Peenisam.

In this preliminary study it was found that **Nilavembu Chooranam** is an effective remedy in the management of Neer Peenisam

This drug is easily available and economical.

It was well tolerated safe and free from any adverse effect.

INTRODUCTION

The disease NINA KURARKAMAL (Enlarged Tonsils) is a world wide health problems is a common problem among children and youth due to neglecting oral hygiene may allows invasion of micro organisms and cause secondary damage to heart valves (Rheumatic Fever) and kindly (glomerulonephritis) it can also leads to skin- rashes, sinusitis, pneumonia and ear infection.

The modern surgical management has more complication and also more harmful to pharynx so safe remedy is need of the day.

The siddha medical science offer time tested experimental knowledge that can provide clues to explore and discover the medicine value of animal origin.

Present study was planned to evaluate the efficacy of **SANGU PARPAM** on Nina kurarkamal [Enlarged tonsils] .

AIM AND OBJECTIVES

The aim of the dissertation work is to assess the efficacy of SANGU PARPARAM IN the management of Nina kurarkhmmal. [Enlarged Tonsils] ‘Strrep throat’(TONSILLITIS) is a specific type of infection caused by streptococcus bacteria can cause Secondary damage to the heart value. (Rheumatic – Fever) and kidney (glomerulonephritis) so. It is need to treat with . herbo-minaral combination of non toxic drug. Sangu Parparam to Prevent cardio vascular Events.

Tonsillitis is one of the commonest and major problem among pediatric population and young adults. Hence SANGU PARPAM was studied in the following aspects.

- ACUTE CHRONIC TOXICITY STUDIES
- BIO CHEMICAL ANALYSIS
- ANTI MICROBIAL STUDIES
- PHARMACOLOGICAL STUDY
- CLINICAL STUDY.

REVIEW AND LITERATURE

rq;F

1) Gunapadam Aspect:

NtWngah;fs;: ee;J Rj;jp ehF tis fk;G NfhL thuzk; nts;is tz;L
,lk;Ghp rq;fk; Njtjj;jk;.

kUj;Jtj;jpw;F gad;gLk; rq;F: CJ rq;F

ngghJ Fzk; : rq;fpdhy; ,uj;j gpj;jk; fz;Nzha;fs; thj;kpFjp frpT
%isfl;b Kjypa Neha; ePq;Fk; grpia cz;lhf;Fk;.

“frpth kpui;j gpj;jq; fz;Nzq; NsUk;

grpahYk; thjk; gwf;Fk; - kprpTINd

jq;F Kisttpuze; jhsfY} Nknts;isr;

rq;fkJ Tz;lhapw;wd;”

Njiuah;

nra;iffs;

cly; cukhf;fp

Jaulf;fp

mfl;Lthafw;wp

grpj;jPj;J}z;b

Jth;g;gp

ntg;gfw;wp

Nfhio mfw;wp.

kfpikah ke;jhur; rpiyKl; rq;F

khq;fpr;rpjy kufjkhq; FUtt; lg;gh

Nghfh; fhurhuj;Jiw

cgurq;fs; 120 fPo; rq;F tifg;gLj;Jgl;Ls;sJ.

gQ;rg+j cgurk; : rq;F : mg;G

mg;Gtpd; Fzk; :

fhrkWk; je;jq; foyhJ NkfKjy;

tPR kzy; jzpAk; tPhpakhk; - thrnk

ce;jptsh; Fz;k KepuQ; nrhwpapitNghk;

,e;ehWe; jz;zPUf;Nf.

jz;zPhpdhy; fz; fhrk; , gpj;j gpuNkfk; gpj;j Fd;kk; ntl;Lfhaq;fspypUe;J

ngUFk; FUjp nrhwp Mfpait NghFk;. gw;fs; cWjpngUk;

“frpthk; ,uj;jgpj;jk; fz;Nzha;fz; MFk;.

Grpahwk; thjk; gw;Fk; - ,rpTINd

jq;F ehNdh tpuze;jd; mfYNk nts;s

rq;fkJ cz; Nlah; ehd;”

mfj;jpah; ml;ltidthflk;.

[e;J Rz;zk;

- cNyhfd; cUf;fTk; Ntijapy;

ruf;Ffis vhp;fTk; gad;gLk;

rq;F NrFk; gpwkUe;;Jfs;

jPUk; Neha;fs;

fhu kUe;J

- %yk;

Rq;F ePh;

- Fd;kk; gf;f R+iy

Jj;jik

- fz;Nzha;;fs;

jhk;gguhjp khj;jpiu

- rfytpj fz;Nzha;fs;

,uj;jpdjp khj;jpiu

- Jh; khkprk; fhr Nuhfk; mkuk;

gQ;r ghzurk;

- [yNjhrk;

jpiuNyhf;fpa rpe;jhkzp urk;

- mf;fpdpgyk;

,yFuh[kpUfhq;fk;

- fhrk; uh[\ak;

thj ur \$y khj;jpiu

- fopr;ry;

thf;fg;gl;l uj;jpdhjp khj;jpiu

- fz;Nzha;fz;

fNde;jpuhjp khj;jpiu

- fz;Nzha;fz;

rq;F gw;gk;.

- Rthr fhrk;

%is ,uzj;jp;w;U

Ky;iyapd; eifaha; rq;fj;jpd; gw;gk;

%isapd; ,uz Neha; Nghf;Fk;

itj;a rjfk;

TAXONOMY

KING DOM	:	ANIMALIA
BRANCH	:	PROTOSTOMIA
PHYLUM	:	MOLLUSCA
CLASS	:	GASTROPODA
ORDER	:	NEOGASTROPODA
FAMILY	:	TURBINELLIDAE
GENUS	:	XANCUS
SPECIES	:	PYRUM

XANCUS PYRUM

OTHER NAMES

SANSKRIT	:	SHANKHA
ENGLISH	:	CONCH SHELL
DUK	:	SUKK
GUJ, MAH, KON, GUN	:	SHANKHA
TEL	:	SEHKHAM

BEN : SANKH.

DISTRIBUTION

Abundantly found in South east coast of India, Areas of gulf of mannar , Palk-bay (T.N. Coast) and Gulf of Kutch.

CHARACTERS :-

A Porcelaneous shell of an oblong or conical form the oblong form is bulged in the middle and tapering at each end and the conical variety is tapering at each end and the conical variety is peculiar the upper portion is like cork screw, twisted and tapering at the end. The base is broad, the interior is hollow the surface is hard of a dull white color the Upper surface is highly tuberculated.

MEDICINAL USES

Shankha parpam . C. Silicate of Magnesia) does is 2- 6 grains used for ear ache ulcers, eye troubles and internally for dysentery . gonorrhea , colic dyspepsia and jaundice , tympani ties.

A compound powder made up of shanka parpar with 5 bodice seed, 4asofodida 3 trikaduku and rock salt 4. Each part make it as powder used in colic pain in abdomen.

Shank parpam .Ficus religiosa, Borax and aconite is used in catarrh, sore throat, cough asthma etc. Does is 2 grams.

Kaphakettu rasa containing conch shell lime is also useful in discharge from ears nose etc. It is used as an expectorant a relives the phlegm. and fever.

cj;jhkzp

PERGULARIA EXTENSA (JACG)

NtWngah;fs; : NtypgUj;jp cj;jkhhfhzp cj;jk fd;dpif fPhplk;

gad;gLk; cWg;G : ,iy nfhb

Rit : ifg;G

jd;ik : ntg;gk;

gphpT : fhh;g;G

nra;iffs;:

- | | | | |
|----|-----------------|---|-------------|
| 1. | Nfhioafw;wp | - | Expectorant |
| 2. | Gof;nfhy;yp | - | Germicide |
| 3. | the;jpAz;lhf;fp | - | Emetic |

Fzk;

Mypj;njoe;j Neha; mj;jidAe;jPUk;

Ntypg; gUj;jpajpd; nky; ,iyahy; - Ntnyj;Jf;

fz;bf;Fk; thjq; fLQ;rd;dp NjhIKk; NghFk;

cz;bf;Fk; thridahk; XJ.

mfj;jpah; Fzthflk;

nghopg;Giu:

tspf;Fw;wj;jhYz;lhFk; Neha;fs; Filr;ry; Fj;jy; tPf;fk; eLf;fk; typ Nghd;w
Neha;fSk; ,iug;G ,Uky; Nfhiof;fl;ly; Mfpa Neha;fSk; jPUk;

tof;F Kiwfs;

cj;jhkzp FbePh; - [yNjhrrf;jpdhy; cz;lhFk; thj gpj;j rd;epfspd;
Njhl tplq;fs; ahTk; ePq;Fk;
,jd; ,iyr;rhwiw Rz;zhk;G fye;J fhy; tPf;fq;fSf;Fk; Nghlyhk;
,iyapd; tpOijg; gpsitf;Fl;L itj;Jfl;lyhk;
,jd; ,urk; 5 JspAk; Njd; 5 JspAk; Nrh;j;J jhkpu nre;J}uk; 12 kpfp cld; f];Jhp
12.kpyp Nrh;j;J nfhLf;f Rthr; jPUk;.
,J Rz;zhkhf;Fk; nrb ,jdhy; nra;ag;gLk; gw;gk; kpf fhukha; ,Uf;Fk;
cj;jhkzpr;rhw;why; rhW fhJ typ jPUk;.

cj;jhkzp NrUk; gpw kUe;Jfs;

jPUk; Neha;fs;

fz;lf;fj;jphp Nyfpak;	- Rthr fhrk;
Gdh;thjp Ruzk;	- fhrk; rpNyj;Jkk;
NtypgUj;jp mil	- ,Uky;
etr;rhuk; ,e;Jg;G ntq;fhuk;	
NtypgUj;jp; miuj;J Njdpj	- cz;ehf;F tsh;r;rp

cz;ehf;fpy; jlt

trk;G khj;jpiu

- Foe;ijfspd; tapw;W typ

fw;Rz;zhj;ij cj;jhkzp rhwwpy; jhspj;J jpdk; ntw;wpiyapy; jltp jhk;Gykhf
gad;gLj;j fgrd;dPthA jPUk;.

FUgw;gk;

- cj;jhkzpr;rhW – thA jPUk;

mRtfe;jp vz;nza;

- fhJtyp jPUk;

BOTANICAL ASPECTS

TAXONOMY

KINGDOM : PLANT KINGDOM
DIVISION : ANGIOSPERMS
CLASS : DICOTY LEDONAE
SUBCLASS : GAMOPETALEA
SERIES : BICRAPELLATEA
ORDER : GENTIANALES
FAMILY : ASCLEPIADACEAE
GENUS : PERGULARIA
SPECIES : DAEMIA

(SYN : PERGULARIA EXTANSA)

VERNACULAR NAMES

SAN	:	PHALA KANTAK
HINDI	:	UTRANAJUTUKA
PUNJ	:	TROTTOO
AUJ	:	NAGALADUDHELI
BEN	:	CHHAGAL BATI
SIND	:	KHARYAL DNDHAVELA
KAN	:	ATTARANI : UTARNI
TEL	:	JITTUPAKU GURTICHETTU
MAL	:	VELIPERITEE
CAN	:	TALAVARANABALL

HABIT : This common tawnier is found throughout India,

PART USED : whole plant- leaves roots and root bark.

CONSTITUENTS : Leaves contain Daemiae Alkaloid Soluble in ether alcohol and not Criztalisable The ash from the dried leaves powder has found amount 15.33% Pc and bitter glycoside also present.

MEDICINAL USES

Decoction of the Leaves is given to children as an anti helmintic. In does it is a good expectorant. Juice of leaves is useful also in asthma and snakebite.

Powdered leaves in does of 5- 10 grain are also good expectorant.

Externally the juice combined with lime is applied to Rheumatic swelling. Honey is also added to the decoction of the leaves to help the expectorant effects (chopra) combined with ginger the juice of the leaves is given to the rheumatism .

Fresh Lanes made in to a pulp are used as a stridulating poultice in carbuncle with benefit.

epzw;Fuw; fk;ky;

njhz;ilf; fl;L Rugq;fk; vd NtW ngah;fshy; Fwpg;gplg;gLk; Fuw; fk;ky;
Nehapd; xU gphpthFk;.

cz;zhf;F mow;rp njhz;ilf;fpue;jp tPf;fk;> yrd jhgpjk;. (mz;zhf;F J}W vd;W)
miof;fg;gLk; Nehapd; Fzq;fs; lhf;lh; R.jpahfuh[d; Fzghlk; jhJ rPt tFg;gpy;
gf;fk; 487y; Fwpg;gpl;Ls;s Enlarged Tonsils mz;zhf;F J}W Nehapd;
FwpFzq;fSk; mbg;gilapy; xd;Nw vd;Wk; mz;zhf;F cz;zhf;F xNu Nehia
Fwpg;gpLtjhf fjpuNth; gps;is jkpo; nkhop mfuhjpapy; njhFjp – 1 y;
Fwpg;gpl;Ls;shh;. NkYk; cz;zhf;F mow;rpAk; epzFuw;fk;ky; Nehapd;
FwpFzq;fSk; xNu Nehapid Fwpg;gpLtjhf cs;sJ.

Neha; tUk; top

1. Fsph; fhw;wpyPLgly; Fsph;e;j nghUs;fis cl;nfhs;sy;

2. njhz;ilapy; Gz;gljf;f R++l;by; nte;ePh; gUFjy;

,r;nrayhy; njhz;ilapy; ,Ugf;fq;fSk; jhgpij;ij cz;lhf;fp, Fuy; tisapd; tPf;fk; ,
njhz;ilapy; , rij tsh;jy; njhz;il Gz; , ,Uky; Nghd;w FwpFzq;fs; Vw;gLk;

FwpFzk;

Fuy;tis epzf;Nfhio nfhz;L el td; Nghy;
tpuT t*g; igf;Uz;ePh; Ntl;if jUNky;
tzg;Ngh; rwptpz;ik thw; nghWj;J Ngry;
epze;Fuw; fk;k ndwp

1. njhz;il rpte;J lak; \$ba njhz;ilapy; rij tsUk;
2. ,r;rij tsh;r;rp fl;bfs; Nghy; gFj;J Fuw;fk;ky; Nehia cz;lhf;Fk;.
3. Ruk;> njhz;il typ tha; ehw;wk; %f;fpy; ePh; tbjy;, fhjpy; rPo; tUjy;>
,Uky; %r;Rj; jilg;gly; Kjypa Fw;Fzq;fis Vw;gLj;Jk;.
4. ePh; czT tpOq;f Kbahik

Kf;Fw;wk;.

la kpFe;J cjhd thAtpd; jd; td;ikia ,of;fr;nra;Ak;

ehb

“jhNdKs;s Nrj;Jke; jhdpsfpy;
..... neQ;rilg;G
,jNkhL ,Wjpehb ,yfplh epWjp epd;why;
gjnhL njhz;il fl;Lk; gOj;JneQ;jdpw;fl;Lk;”

Fz thfl ehb

MATERIALS AND METHODS

DRUG PREPARATION

SOURCE OF COLLECTION :- Sangu (Conch shell) Raw drug was purchased from the raw drug shop at Chennai.

PURIFICATION OF SANGU : (CONCH SHELL)

Conch shells were broken into smaller pices and purified by saturated clear solution of karchunnam [calcium carbonate] immersed for 24hrs and boiled, then washed with water and dried.

PREPARATION OF PARPAM AND STORAGE

The purified dried conch shell placed in the uthamani karkam. in a earthen disc then it was boiled well kept for 3 days in the sun light and covered with same. It was sealed with seven layers of clay cloth and dried, then it was subjected to pudam final calcination the parpam . further granined well into fine particles and sieved in white cloth (vastharakeyam) and kept in dry clean air light container [Ref. Dr. Thiagarajan. Thathya seeva gunapadam Part II]

TEST DRUGS

The following medicinal plants were used in the study were collected and processed by the methods prescribed in standard text books of siddha medicines.

Sangu Parpam [SGP]

was prepared by the method described in [Gunapadam Thadhoo Seeva Vaguppu

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TOXICITY STUDY

1.1 Preparation of drug for dosing

All drugs used for the study was suspended each time with 1% (w/v) solution of sodium carboxyl methyl cellulose before administration.

1.2 Drugs and chemicals

Histamine hydrochloride and fine chemicals used in these experiments were obtained from Sigma Chemicals company, U.S.A. Other analytical grade chemicals were obtained from S.d. Fine Chemicals Ltd., Mumbai.

1.3 Experimental animals

Colony inbred animals strains of wistar rats of either sex weighing 200 - 250 g were used for the pharmacological and toxicological studies. The animals were kept under standard conditions 12:12 (day/night cycles) at 22⁰C room temperature, in polypropylene cages. The animals were fed on standard palliated diet (Hindustan Lever Pvt Ltd., Bangalore) and tap water *ad labium*. The animals were housed for one week in polypropylene cages prior to the experiments to acclimatize to laboratory conditions. The experimental protocol was approved by the Institutional Animal Ethical Committee (IAEC).

1.4 ACUTE ORAL TOXICITY STUDY

Acute oral toxicity was conducted as per the OECD guidelines (Organization of Economic Cooperation and Development) 423 (Acute Toxic Class Method). The acute toxic class method is a stepwise procedure with 3 animals of a single sex

per step. Depending on the mortality and /or moribund status of the animals, on the average 2-4 steps may be necessary to allow judgment on the acute toxicity of the test substance. This procedure results in the use of a minimal number of animals while allowing for acceptable data based scientific conclusion.

The method uses defined doses (5, 50, 300, 2000 mg/kg body weight) and the results allow a substance to be ranked and classified according to the Globally Harmonized System (GHS) for the classification of chemicals which cause acute toxicity

Wistar albino rats of either sex weighing 200-250 g were fasted overnight, but allowed water *ad libitum*. Since the formulation is relatively non toxic in clinical practice the highest dose of 2000 mg/kg/p.o (as per OECD guidelines “Unclassified”) was used in the acute toxicity study.

The animals were observed closely for behavioral toxicity, if any by using FOB (Functional observation battery).

1.5 REPEATED ORAL TOXICITY STUDY

Repeated oral toxicity studies can be used to get additional information regarding the toxicity profile of a chemical. Repeated oral toxicity studies are defined as those studies where the chemical is administered to the animal for a period covering approximately 10% of the expected life of the animal. Usually, the dose levels are lower than for acute studies and allow chemicals to accumulate in the body before lethality occurs, if the chemical possess this ability.

1.6 Experimental procedure

The following experimental procedure was followed to evaluate the repeated oral toxicity study of -

SANGU PARPAM (SGP)

Group I : Control animals received 1% Sodium carboxyl methyl cellulose (CMC), ml/kg/p.o. for 21 days

Group II : Drugs suspended in CMC was given at the dose Level of 500 mg/kg/p.o. for 21 days

Body weight, food intake and water intake was recorded at two intervals with simultaneous observation for toxic manifestation and mortality, if any. At the end of 21 days treatment all the animals were sacrificed by over dosage of ether anesthesia. Blood was collected and used for hematological studies. Section of liver, kidney, and heart were dissected out and kept in 10% formalin for histopathological studies.

1.7 Acute oral toxicity study

SGP at the dose of 2000mg/kg/po did not exhibit any mortality in rats. As per OECD 423 guidelines the dose is said to be “Unclassified” under the toxicity scale. Hence further study with higher doses was not executed.

1.8 Repeated oral toxicity for 21 days

Test drug SGP at the dose of 500 mg/kg/po when administered orally for 21 days in rats did not show toxicity in renal functions. There was an significant increase in % of Hb and RBC (Table 2). However the drug did not show any significant elevation of marker enzyme levels of liver (Table 3).

TABLE 1
EFFECT OF SIDDHA FORMULATIONS (NVE) ON
HAEMATOLOGICAL PARAMETERS AFTER 15 DAYS REPEATED
ORAL DOSING (500 MG/KG)

Groups	Hb (gm/100ml)	RBC (millions/ cu.mm)	WBC (cells/cu.m m)	Differential leucocyte count (%)		
				Lympho cytes	Mono cytes	Granulo cytes
Normal	13.08 ± 0.34	4.31 ± 0.35	54850 ± 9.44	76.06 ± 3.89	5.30 ± 1.04	16.50 ± 4.27
NVE (500mg/ kg/p.o)	13.68 ± 0.70 ^{ns}	4.68 ± 0.72 ^{ns}	5786.66 ± 3.323	77.67 ± 3.32 ^{ns}	8.16 ± 1.7 ^{ns}	16.66 ± 3.44 ^{ns}

n=6; Values are expressed as mean ± S.D followed by Students Paired 'T' Test

ns – non significant when compared to control groups

TABLE 2
EFFECT OF SIDDHA FORMULATION (NVE) ON BIOCHEMICAL
MARKERS OF LIVER AND KIDNEY AFTER 15 DAYS REPEATED
ORAL DOSING (500 MG/KG/PO) IN RATS

Groups	ALP (K.A.Units)	AST (IU/L)	ALT (IU/L)	Urea (mg/100ml)	BUN (mg/ 100ml)
Normal	3.78±0.38	78.48±0.23	28.70 ± 0.81	13.56 ± 0.37	6.48 ± 0.50
NVE (500mg/kg/p.o)	4.32±0.75 ^{ns}	79.55±5.92 ^{ns}	30.13 ± 2.67 ^{ns}	14.60 ± 0.69 ^{ns}	7.51 ± 0.35 ^{ns}

N=6; Values are expressed as mean ± S.D followed by Students Paired 'T' Test

Ns – non significant when compared to control groups

BIOCHEMICAL STUDIES

ASPARTATE AMINOTRANSFERASE (AST)

Aspartate aminotransferase was estimated using commercial AST kit (Span Diagnostics) by the method of Reitman and Frankel (1957).

Alanine aminotransferase (ALT)

Alanine aminotransferase was estimated using commercial AST kit (Span Diagnostics) by the method of Reitman and Frankel (1957).

Alkaline phosphatase (ALP)

Alkaline phosphatase was assayed using commercial ALP kit (Span Diagnostics) by the method of King (1934).

Urea

Urea was assayed using the commercial kit (Span Diagnostics) by the method of Coulambe *et al.*, (1965).

1.8 Haematological studies

Erythrocyte count

Erythrocyte count was estimated by Hemocytometer method of Ghai (1995).

Total Leukocyte Count (WBC)

Total Leukocyte Count was estimated by Hemocytometer method of John (1972).

Haemoglobin

Haemoglobin was estimated by method of Ghai (1995).

TABLE 3
EFFECT OF SIDDHA FORMULATIONS (SGP) ON
HAEMATOLOGICAL PARAMETERS AFTER 15 DAYS REPEATED
ORAL DOSING (500 MG/KG)

Groups	Hb (gm/100ml)	RBC (millions/ cu.mm)	WBC (cells/cu.m m)	Differential leucocyte count (%)		
				Lympho cytes	Mono cytes	Granulo cytes
Normal	13.08 ± 0.34	4.31 ± 0.35	54850 ± 9.44	76.06 ± 3.89	5.30 ± 1.04	16.50 ± 4.27
SGP (500mg/ kg/p.o)	13.98 ± 0.70 ^{ns}	4.58 ± 0.72 ^{ns}	5686.66 ± 3.323	78.67 ± 3.32 ^{ns}	8.16 ± 1.7 ^{ns}	15.66 ± 3.44 ^{ns}

n=6; Values are expressed as mean ± S.D followed by Students Paired 'T' Test

ns – non significant when compared to control groups

TABLE 4
EFFECT OF SIDDHA FORMULATION (SGP) ON BIOCHEMICAL
MARKERS OF LIVER AND KIDNEY AFTER 15 DAYS REPEATED
ORAL DOSING (500 MG/KG/PO) IN RATS

Groups	ALP (K.A.Units)	AST (IU/L)	ALT (IU/L)	Urea (mg/100ml)	BUN (mg/ 100ml)
Normal	3.78±0.38	76.48±0.23	28.70 ± 0.81	13.56 ± 0.37	6.48 ± 0.50
SGP (500mg/kg/p.o)	4.32±0.75 ^{ns}	89.55±5.92 ^{ns}	32.13 ± 2.67 ^{ns}	15.60 ± 0.69 ^{ns}	7.61 ± 0.35 ^{ns}

N=6; Values are expressed as mean ± S.D followed by Students Paired 'T' Test

Ns – non significant when compared to control groups

PHARMACOLOGY STUDIES

ANALGESIC ACTIVITY

TAIL FLICK METHOD

Withdrawal of tail (Tail Flick) for noxious thermal (radiant heat) can be used for screening drugs with analgesic activity. Radiant heat can be generated by passing electrical current through nichrome wire mounted in an analgesiometer.

The base of the tail of the test rats is placed on a nichrome wire. The tail withdrawal for the radiant heat (flicking response) is taken as the end point. Normally the rats and mice withdraw their tails within 3 – 5 secs. A cutoff time of 10 – 12 secs is used to prevent damage to the tail. Any animal failing to withdraw its tail in 3-5 secs is rejected from the study.

The reaction time of test drug, standard and control are taken at intervals of 30, 60 and 120 mts. A reaction time (withdrawal time) increment of 2-5 secs more than the control animals can be considered for analgesic activity of the drug.

TABLE 5**ANALGESIC ACTIVITY OF SGP USING TAIL FLICK METHOD**

Groups	Paw licking response (Sec)			
	0 min (Sec)	30 min (Sec)	60 min (Sec)	120 min (Sec)
Control	1.56 ± 0.96	1.86 ± 0.96	1.76 ± 0.67	1.86 ± 0.53
Test (500mg/kg. p.o.,)	1.86 ± 0.206 ns	2.367 ± 0.265 ***	4.866 ± 1.267 ***	5.8 ± 0.4336 ***

n=6, Values are expressed as mean ± S.D using followed
by student paired T – test , ns- non significance

P<0.001 as compared with control.

ANTI INFLAMMATORY ACTIVITY

Anti inflammatory activity was evaluated in acute model of inflammation.

Acute model

Carrageenan induced hind paw edema

The carrageenan assay procedure was carried out according to the method of Wintar *et al.* (1962). Edema was induced by injecting 0.1 ml of 1% solution of carrageenan in saline into the plantar aponeurosis of the left hind paw of the rats. The extracts, reference drug and the control vehicle (distilled water) were administered 60 min prior to the injection of the carrageenan. The volumes of edema of the injected and contra lateral paws were measured at +1, 3 and 5 hrs after induction of inflammation using a plethysmometer (Bhatt *et al.*, 1977) and percentage of anti-inflammatory activity was calculated.

TABLE 6
ANTI INFLAMMATORY ACTIVITY OF SGP
INDUCED END PAW EDEMA IN RATS

Groups	Paw volume (ml) by mercury Displacement at regular interval of time					
	0min	30min	60min	120min	240min	15 hrs
Control	1.323 ± 0.1549	1.60± 0.225	1.933± 0.242	2.066 ± 0.258	2.200± 0.236	2.200± 0.236
SGP (500mg/kg. p.o.,)	1.323 ± 0.338 ns	1.67 ± 0.426 ns	2.03 ± 0.2366 ns	1.650± 0.316 ***	1.500 ± 0.312 ***	1.533 ± 0.372 ***
Standard (Dic.Sodium 5 mg/kg/po)	0.835 ± 0.065 ^{ns}	1.315 ± 0.069 ^{ns}	1.128 ± 0.049 ^{***}	1.011 ± 0.056 ^{***}	0.896 ± 0.048 ^{***}	0.85 ± 0.054 ^{***}

n=6; Values are expressed as mean ± S.D followed by student paired T- test. ns - Non significant as compared with control;
P< 0.001 (***) as compared with control.

Results

SGP showed anti-inflammatory activity in carrageen an induced hind paw edema in rats. The anti-inflammatory activity was observed at the end of 2 hrs after the pre treatment drug whereas the standard drug diclofenac sodium exhibited reduction in edema volume at the end of 1 hr after administration.

ANTI MICROBIAL STUDY

Paper disc diffusion method

The sterilized (autoclaved at 120 ° C for 30 min) medium (40-50 ° C) was inoculated (1 ml / 100 ml of medium) with the suspension (10^5 cfu mL⁻¹) of the microorganism (matched to Mc Farland barium sulphate standard) and poured in to a Petri- dish to give depth of 3-4 mm. The paper impregnated with the test compounds (25, 50, and 100 µg mL⁻¹ in dimethyl formamide) was placed on the solidified medium. The plates were pre incubated for 1 h at RT and incubated at 37 ° C for 24 and 48 h for anti bacterial and anti fungal activities, respectively. Ciprofloxacin (100 µg /10 disc) and ketoconazole (100 µg/ disc) were used as standard for anti bacterial and anti fungal activities, respectively. The observed zone of inhibition is presented in table

In-vitro antimicrobial activity of SGP was screened against bacteria and yeast strains. The results are depicted in Table 14. SGP were exhibited low antimicrobial activity in streptococcus mutans in 10 µl / disc. Others were exhibited moderate to high antibacterial activity when compared to standard drugs ciprofloxacin and ketoconazole respectively.

TABLE 7**Zone of inhibition in mm**

Organism	Standard drug Ciprofloxacin 50 mcg/disc	Test drug (SGP μl/disc)		
		Zone of inhibition in mm		
		10μl	25μl	50μl
Strep. mutans	31	14	16	19
Staph. aureus	31	15	20	23
E.coli	30	16	23	26
K.pneumoniae	31	16	20	24
Ps.areginosa	30	16	19	23
Group A Streptococcus.	31	15	17	22

14 mm – Low sensitive, 15 mm – Moderate, above 16 mm – Highly sensitive

Note Sample concentration :-

4 gm – 400 ml of solvent in 25 μ l, 50 μ l, and 100 μ l / disc standard for Bacteria

;- Ciprofloxacin HCl, 50 mcg / disc.

In-vitro antimicrobial activity of SGP as screened against bacteria and yeast strains. The results are depicted in Table 13. In 10 μ l/disc concentration of SGP were exhibited low antibacterial activity in Group A streptococcus and Staph. aureus. others were exhibited moderate to high antibacterial activity when compared to standard drugs ciprofloxacin and ketoconazole respectively.

ANTIOXIDANT STUDY

1.10 In Vivo Antioxidant study

Samples of serum collected from rats treated with test drugs were assayed for GSH (Moron *et al* , 1979) and LPO (Yagi, 1976) and the results were compared with control group.

Table 8

**Anti oxidant activity of Siddha Formulation (NVE)
after 15 days repeated oral dosing (500 mg/kg)**

Groups	LPO	GSH
Control	0.63 ± 1.37	46.28 ± 2.31
NVE (500mg/kg/p.o)	0.42 ± 3.90 ^{***}	83.31 ± 0.35 ^{***}

N=6; Values are expressed as mean ± S.D followed by Student T- Test.

^{***}P<0.001 as compared with control.

2.6 ANTIOXIDANT ACTIVITY

At the end of 21 days repeated oral toxicity study when the plasma of drug treated animals was examined for GSH activity, the level of GSH activity was increased significantly ($p > 0.001$) in test groups. On the other hand the LPO activity was considerably reduced in drug treated group when compared to control.

CLINICAL ASSESSMENT

1. STUDY DESIGN

1. Open clinical trial
2. Parameters for evaluation

2. SYMPTOMS AND SIGN

Thondai vali [pain]
Vizingupothu vali [pain on swallowing]
Thondai sathai veekam [Enlarged tonsils]
Kurarkammal [Change of voice]
Thondai Sivathal [Redness of Pharynges]

3. LINE OF TREATMENT

Dose : 260 mg bid twice daily Anupanam: honey
Route of administration enternal
Duration : 45 days

4. SELECTION PATIENTS:

Sample size 24 patients total number of number of 24 patients total number of 24 patients are selected on the basis of inclusion and exclusion criteria .

INCLUSION CRITERIA

1. History sign and symptoms of Ninakurarkammal
2. Age between 10-50 years from either sex

EXCLUSION CRITERIA

1. Quinsy
2. Parapharyngea abscess
3. Rheumatic fever endocardities
4. Acute glomerulo nephritis
5. Septicemia
6. 10 t who have any offer concomitant illness
7. 10t with know liver or kidney disorders

DIAGNOSIS

Diagnosis is made by physical examination signs and symptoms of the Disease.

LABORATORY DIAGNOSIS

Blood 1) Leukocytosis [12,000 cells/cumm – 20000cells/cumm]

With predominant polymorphonuclear cells

2) ESR is Raised

Rapid detection method for streptococcal antigen or by culturing after pharyngeal

swabbing, may be positive for streptococci in streptococcal tonsillitis.

BLOOD TEST FOR

➤ **TCL**

➤ **DC**

➤ **ESR**

➤ **HB**

URINE

ALB

SUG

DEP

MEDICAL ADVICE

Advice regarding personal hygiene

Improving general health

All the 24 patients were subjected for the clinical study age socio economic status personals habits and diets occupational status signs and symptoms during admission where recorded improvement showing signs and symptoms and statistical analysis after treatment is recorded and tabulated as follows.

Table 9
SEX DISTRIBUTION

S.N	SEX	No of Patients	Percentage
1	Male	11	45.8
2	Female	12	50
3	Children's	1	4.2
	Total	24	100

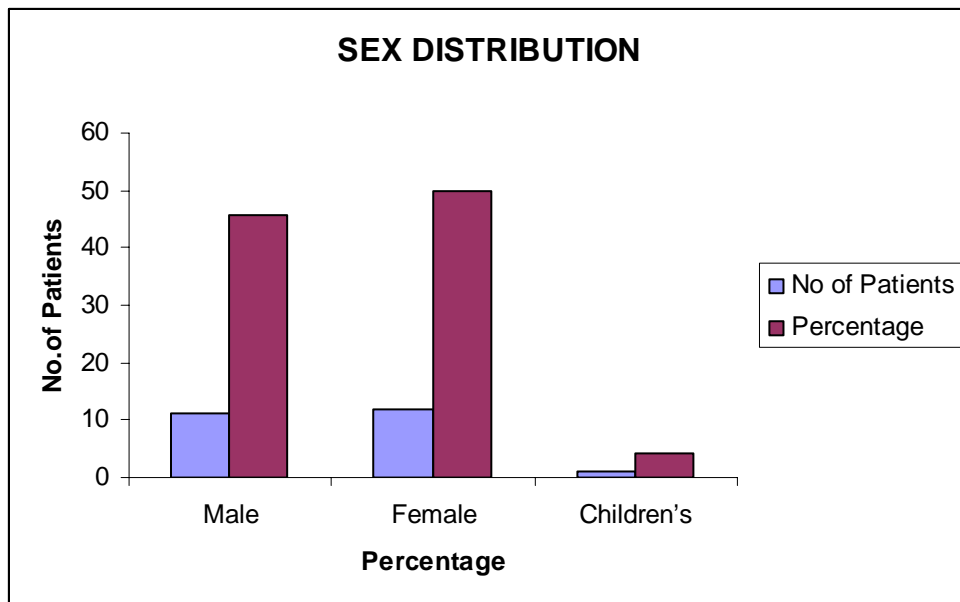


Table 10

AGE WISE DISTRIBUTION

S.N	Age in years	No of Patients	Percentage
1	10 – 20	16	66.6
2	21 – 30	6	25
3	31 – 40	1	4.2
4	41 – 50	1	4.2
	Total	24	100

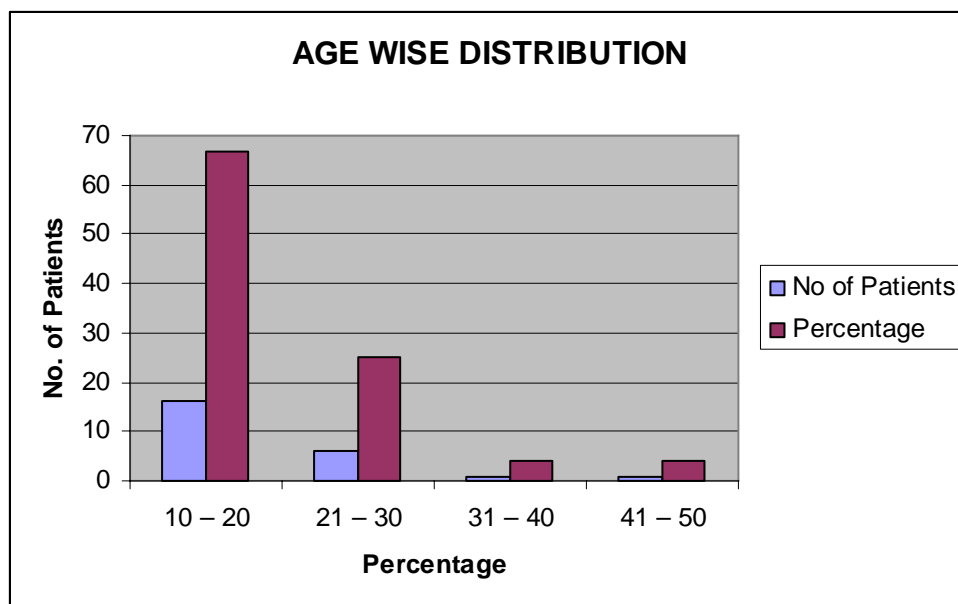


Table 11
SOCIO-ECONOMIC STATUS

S.N	Eco. Status	No of Patients	Percentage
1	Poor	3	12.5
2	Middle	20	83.3
3	Rich	1	4.2
	Total	24	100

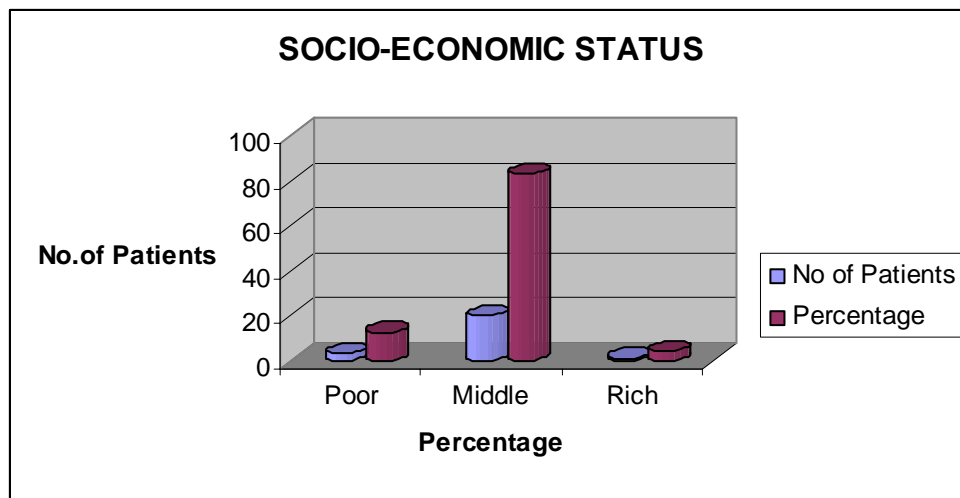


Table 12

DIET

S.N	Diet	No of Patients	Percentage
1	Vegetarian	1	4.2
2	Mixed Diet	23	95.8
	Total	24	100

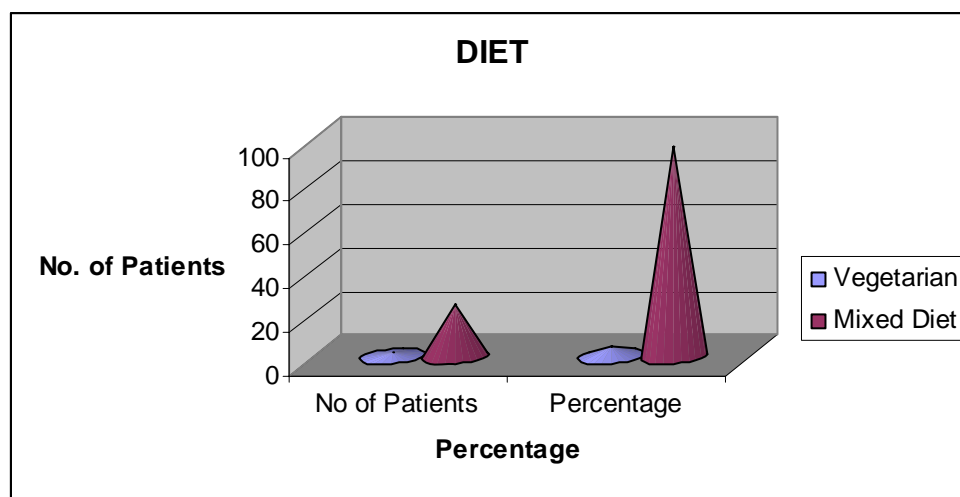


Table 13

OCCUPATIONAL STATUS

S.N	Occupation	No of Patients	Percentage
1	Daily Labor's	5	20.8
2	Students	6	25
3.	House wife	5	20.8
4.	Office worker	5	20.8
5	Business	3	12.6
	Total	24	100

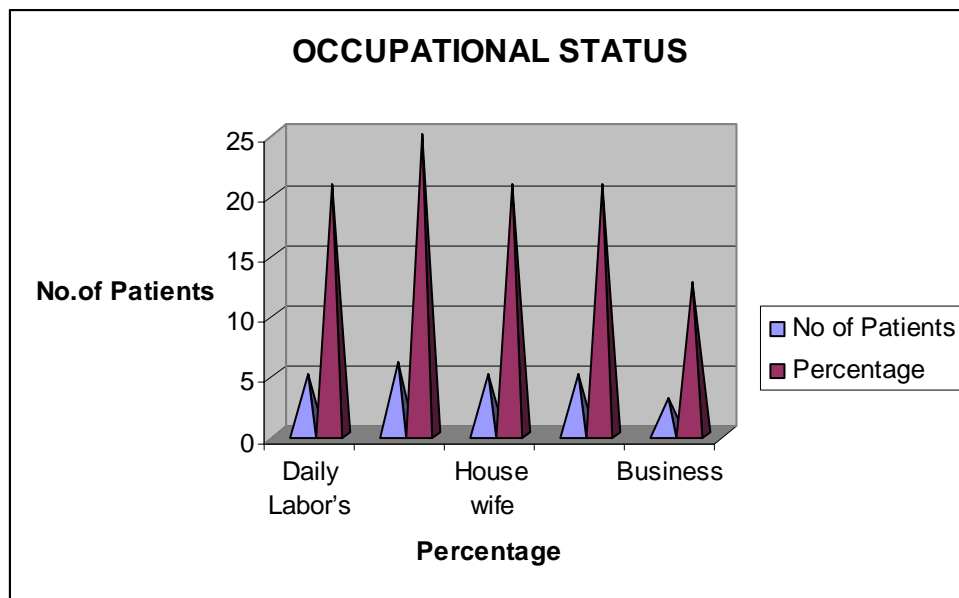


Table 14

**IMPROVEMENT OF SIGNS AND SYMPTOMS
OBSERVED BEFORE AND AFTER
TREATMENT OF 24 (N)
PATIENTS OF NINAKURAR KAMAL GSMC, CHENNAI – 106.**

S.NO	SIGNS AND SYMPTOMS	NUMBER OF PATIENT		PERCENTAGE
		Before Treatment	After Treatment	
1	Throat pain	24	3	87.5
2	Cough	20	4	80
3	Change of voice	15	3	80
4	Enlarged tonsils	12	3	83.33

Table 15

**RESULTS OF STATISTICAL ANALYSIS OF
SUBJECTIVE PARAMETERS OBSERVED
BEFORE AND AFTER TREATMENT
OF 24(N) PATIENTS OF NINAKURARKAMAL GSMC, CHENNAI**

S/n	Parameters	Mean value		Difference Present	Statistical Test criteria	Probability (P) Value	Statistical significance
		Before Treatment	After Treatment				
1.	Throat pain	34.0± 3.577	3.0± 0.894	21.0± 3.128	16.432	0.001	Significant
2.	Cough	20.0± 4.472	4.0± 1.7889	16.0± 3.621	10.954	0.001	Significant
3.	Change of voice	15.0± 4.472	3.0± 0.894	12.0± 2.752	8.2161	0.001	Significant
4.	Enlarged tonsils	18.0± 1.788	3.0± 0.894	15.0± 2.872	24.648	0.001	Significant

Values are compared with test one sample student T.test

SUMMARY

The Sangu Parpam [SGP] was taken to evaluate its efficacy on Ninakurarkammal.

Zoological and Botanical of the raw drugs were studied regarding its identification and description.

The Sangu Parpam prepared indicated for treating Ninakurarkamal enlarged tonsils which comes under kabha disease. So the plan to evaluate the therapeutic efficacy of this drug in Ninakurarkamal patients, carried out at Aringnar Anna Hospital post graduate Gunapadam out patient department Chennai – 106.

Bio Chemical analysis the SGP Contains Calcium, Carbonate, Chloride.

The pharmacology analysis showed that the drug has got mild anti inflammatory analgesic, antihistaminic, pyuretic animal study the clinical study was done in 24 patients after 45 days course of treatment good response was observed in 18 cases 3 cases showed fair response 3 cases showed poor response.

The drug Sanguparpam is statistically significant in improving Ninakurarkammal digest signs and symptoms

DISCUSSION AND CONCLUSION

The incinerated Sangu parpam SGP Considered to be KARPPU [Acrid] Taste. Which is Normalizing the Kaba thodam in Ninakurarkammal.

Even honey the adjuvant for the drug has expectorant and antiseptic action SGP Exhibition anti- inflammatory and analgesic activities in appropriate experimental models. The delayed anti- inflammatory activity of SGP in carrageenan induced edema may be due to the delayed absorption of activity constituent of the drug from GI tract or a mechanism by which SGP inhibits the synthesis or release of inflammatory prostaglandins from the site of chemical injury (carrageenan) SGP exhibited analgesic activity in the radiant heat method in rats. There is a good correlation of results obtained from the experimental study vi-a-vis the clinical study reported in the thesis.

The total leukocyte count and ESR are indicates level of infection associated with infection dropped to normal. Proving that Sangu parpam had influenced the disease state So it is concluded that for the disease Ninnakurakammal the treatment with Sangu Parpam is good in the view of efficacy and safe.

It was found that Snagu Parpam is an effective remedy in the management of Ninakurarkamal discus is easily available and economical. It was well tolerated, safe and free from any adverse effect.

CLINICAL STUDY ON SANGU PARPAM IN O.P DEPARTMENT IN THE MANAGEMENT OF NINA KURAR KAMAL																
														Result		
S/N	OP.N O	NAMES AGE/SEX	COMPLAINTS	B/T A/T	TLC	Blood			URINE							
						DC (%)			ESR (MM)		HB %	HB	SUG	DEP		
						P	L	E	1/2 HR	1 HR						
1	1414	Jothika 30/F	Throat Pain Fullness in the Throat . Malise	BT	10100	53	39	8	22	45	10.2	N	N	OPC	Good	
				AT	11600	51	35	8	10	30	12.5	N	N	OPC		
2	1493	Mani 20/M	sore Throat difficulty in swallowing	BT	8900	54	40	6	7	14	10.5	N	N	N	Good	
				AT	8800	58	38	6	3	7	11	N	N	N		
3	1500	Balu 21/m	Cough. Change of voice sore throat	BT	11200	56	32	12	38	65	12.5	N	N	N	Moderate	
				AT	10600	56	38	6	22	40	13	N	N	N		
4	1502	Srinivasan 19/F	Throar Pain Cough Feverish	BT	10300	58	30	12	12	25	14	N	N	N	Good	
				AT	10000	51	47	2	7	15	14	N	N	N		
5	1856	Bharathi 10/M	Loss of appetite cough sore throat	BT	9100	58	40	2	5	12	12	N	N	N	Good	
				AT	9000	60	38	2	5	10	12	N	N	N		
6	1826	Tamilselvi 23/F	Difficulty in swallowing malise sore throat	BT	12600	52	42	6	15	30	12.2	N	N	FEC	Moderate	
				AT	11200	54	40	6	10	20	12.3	N	N	FEC		
7	1831	Gokul 15/M	Throat pain Cough, Malise running Nose	BT	11600	52	38	10	29	52	13	N	N	N	Good	
				AT	10600	54	37	7	5	11	13	N	N	N		
8	2091	Aswini 19/F	Sore throat cough headach	BT	10200	70	22	8	40	120	11.5	N	N	FEC	Mild	
				AT	11058	58	40	2	34	70	11.5	N	N	FEC'		
9	2089	Ravichandran 16/M	Throat pain cough lose of appetite	BT	8800	52	41	7	22	60	13.5	N	N	N	Good	
				AT	8600	54	40	6	18	40	13.5	N	N	N		
10	2123	Sankar 19/M	Throat pain difficulty in swallowng malise	BT	10800	64	31	5	18	40	13.5	N	N	N	Good	
				AT	10400	65	32	3	10	18	13.5	N	N	N		
11	2096	Vadivelu 17/F	Sore throat nasal Discharge cough	BT	10700	62	33	5	6	12	14	N	N	N	Good	
				AT	10100	65	33	2	6	11	14	N	N	N		
12	2152	Rajesh 20/M	Throat pain difficulty in swalling	BT	12200	56	40	4	15	32	14.2	N	N	N	Good	
				AT	11600	58	38	4	6	12	14.2	N	N	N		
13	2147	Rajasekar / 17/M	Sore throat fever , cough	BT	10200	53	39	8	44	70	13.5	N	N	N	Good	
				AT	10000	62	33	5	15	25	13.5	N	N	N		

14	2917	Suselar 19/F	Cough Throat pain malise	BT	10000	60	35	5	60	124	12.8	N	N	FEC	Moderate
				AT	9600	62	33	5	35	68	12	N	N	FEC	
15	3070	Vasu 17/M	Fullness in the Throat , Malise sore throat	BT	10600	48	38	14	12	26	4	N	N	N	Mild
				AT	9800	52	38	10	5	11	14	N	N	N	
16	3067	Sudalakrishmi 16/F	Throat Pain cough	BT	11200	48	40	12	40	80	11.5	N	N	OPC	Moderate
				AT	11400	50	40	10	45	90	11.5	N	N	OPC	
17	4401	Masilamani 19/M	Throat pain dysphagia loss of appetite	BT	12100	56	38	6	16	34	13	N	N	N	Good
				AT	10400	58	38	4	20	42	13	N	N	N	
18	4389	Vimala 20/F	Sore throat headache ear discharge	BT	9700	59	35	6	22	40	10.5	N	N	FEC	Good
				AT	9000	70	36	4	5	11	11	N	N	FEC	
19	5837	Sowmya 22/F	Cough Sore Throat,	BT	9200	54	41	7	10	20	9.5	N	N	OPC	Good
				AT	8600	56	35	5	55	11	9.5	N	N	OPC	
20	5921	Nazhima	Throat Pain Fullness of throat Feverish	BT	9000	58	38	6	12	25	9	N	N	FEC	Mild
				AT	9600	56	36	6	12	26	9	N	N	FEC	
21	6454	Kamatchi 37/F	Throat pain oral ulcer cough	BT	9000	56	38	6	11	25	9.5	N	N	FEC	Good
				AT	8100	55	37	8	6	12	9.5	N	N	FEC	
22	6366	Tharuniza 37/F	sore throat cough nasal discharge	BT	8600	56	38	6	11	25	10.5	N	N	OPC	Good
				AT	8100	61	35	4	6	14	11	N	N	N	
23	6828	Jeyaganesan 27/M	Throat pain difficulty in swallowing cough	BT	11800	60	39	1	21	40	14.5	N	N	FEC	Good
				AT	9600	55	36	9	12	24	14.5	N	N	N	
24	7221	Johnson 44/M	Fever sore throat malise	BT	13200	48	42	10	30	64	13.5	N	N	OPC	Poor
				AT	13400	52	42	6	40	85	13.5	N	N	OPC	

Abbreviation :

BT - Before Treatment, AT - After Treatment, TC - Total WBC Count, DC - Differential Count, Hb - Haemoglobin, Alb - Albumin, Dep - Deposit, OPC - Occasional Pus Cells, FPC - Few Cells, FPC - Few pus cells, N- Nil, P - Neutrophils, L - Lymphocyte, E - Eosinophils.

BIBILO GRAPHY

1. குணப்பாடம் மூலிகை வகுப்பு தொகுதி – I இந்திய மருத்துவம் மற்றும் ஹோமியோபதித் துறை – சென்னை. டாக்டர் முருகேச முதலியார் வைத்திய மலை அகராதி B.இரத்தின நாயகர் அன்ட் சன்ஸ். சென்னை-79.
2. டாக்டர் S.சோமசுந்தரம், M.se, P.hd. மருத்துவ தாவரவியல் பகுதி – II (ஆஞ்சியோஸ் பெர்ம்களின் வகைபாடு) இளங்கோவன் பதிப்பகம் பாளையங்கோட்டை – திருநெல்வேலி
3. சித்த மருந்துகளின் செய்முறை இம்ப்காப்ஸ் திருவான்மியூர் – சென்னை.
4. டாக்டர் அப்துல்லா சாயுபி அணுபோக வைத்திய நவநிதம் 8 ம் பாகம் பழனி தண்டாயுதபாணி நூல் வெளியீட்டுக்குழு – பழனி
5. S,ராமசுந்திரன் அகஸ்தியர் வைத்திய ரத்தினச் சுருக்கம் தாமரை நூலகம்– சென்னை
6. Dr.R. தியாகராஜன் Lim குணப்பாடம் தாது சீவவகுப்பு இந்திய மருத்துவம் மற்றும் ஹோமியோ பதித்துறை, சென்னை – 106.
7. Dr. Ambika Shanmugam Fundamental of Biochemistry Karthik offset Printer Chennai.
8. கண்ணுசாமி பிள்ளை பதார்த்த குணவிளக்கம் (தாது வர்க்கம்) இந்திய மருத்துவம் மற்றும் ஹோமியோபதித்துறை வெளியீடு.
9. Research obstract Ayur mediline 2000 may
10. Indian Journal of Medical Research Vol

11. சித்த மருத்துவாங்க சுருக்கம் க.அ. உத்தமராயன் - தமிழ் நாடு சித்த அறிவியல் மேம்பாட்டுக் குழு வெளியீடு - 1983 பக் : 140-160
12. சித்த மருத்துவம் க. நா. குப்புசாமி முதலியார் தமிழ் நாடு சித்த மருத்துவ வாரியம் வெளியீடு பக் : 186 - 196
13. சித்த வைத்திய திரட்டு இந்திய மருத்துவம் மற்றும் ஓமியோபதித் துறை வெளியீடு பக் : 272
14. சித்த அறுவை மருத்துவம் ஆசிரியர் டாக்டர். க.சு. உத்தமராயன் H.B.I.M வெளியீடு இந்திய மருத்துவம் - ஓமியோபதித் துறை வெளியீடு பக் : 167 - 170
15. அகத்தியர் அட்டவணை வாகடம் டாக்டர். ச. அரங்கராசன் பி.ஐ.எம் பக் : 54,81,151,401,402
16. யுகி வைத்திய சிந்தாமணி, டாக்டர். ஆர். தியாகராசன் பக் : 183 - 186
17. தேரையர் வாகடம் - பழநி தண்டாயுத பாணி சித்த மருத்துவ வெளியீடு பக் : 125, 126
18. அகத்தியர் 2000 இந்திய மருத்துவம் மற்றும் ஓமியோபதித் துறை வெளியீடு பக் : 136
19. சரபேந்திர வைத்திய ரத்தினாவளி, சரசுவதி மகால் நூல் நிலையம் தஞ்சாவூர் (1985) பக் : 275 - 405
20. வைத்திய சதகம், ஆசிரியர். அமிர் மு. அப்துல்லா சாயுப் பக் : 7, 45.

- 1) Siddha formulary of India.
- 2) Glossary of Indian Medicinal plants Chupra. R.N. Nayarr S.L. and Chopra I.C. C.S.I.R New Delhi (1965)
- 3) Indian Materia Medica. Nadlcarni K.M Popular Prakashan Pvt. Bombay (1982)
- 4) Taxonomy of Vascular Plants Lawrence H. . Oxford & IBH Publising Co, New Delhi (1969).
- 5) Data base on Medician Plants used in Ayu Ayush Jankpuri New Delhi Vol – IVPag 34-38.
- 6) Clinical and Practical Otorhno – Larxngology DR. M. Kumraesan Chennai – 05(1992)
- 7) Indian Herbal Pharmawpeia Vol I Pages : 18,21,23,25,26,27 a joint publication of Regional laboratory and Indian Drug manafactorer's Mumbai – 18.
- 8) The review natural products by Facts and Comparisions.
- 9) [www. indena.h/fitrp.html](http://www.indena.h/fitrp.html)

REFERENCES

Barham D and Trinder, P. Analyst 1972;97:142.

Coulambe G.G and Favrean L.A. Clin. Chem., (1965), 11, 624.

Ghai C.L. A text book of practical physiology, Jaypee Brothers, India 1995; p.119-202.

John MB. Laboratory Medicine Haematology. 4th Ed. C.V. Mosby co, St. Louis, 1972; p.1198-1209.

Kanai L Mukherjee. A text book of medical laboratory technology. A procedure manual for routine diagnostic tests. Tata McGraw Hill Publishing company ltd. 1999; 1: p.242-276.

King E.J and Armstrong A.R (1934), Can. Med. Ass. J., 31, 376.

Kulkarani SK. Handbook of Experimental Pharmacology 2005, Vallabh Prakasan, Delhi.

Moron M.S, Difereee J.W and Mannerwik K.B. Levels of glutathione, glutathione reductase and glutathione s- transferase activities in rat lung and liver. Biochem. Biophys. Acta 1979;582:67-68.

Reitman S and Frankel S (1957), Am. J. Clin. path., **28**, 56

Tenscher, A and Richterich, P. Schweiz Med. Wschr. 1971 : 101:345 and 390.

Yagi K. Simple fluorimetric assay for lipid peroxide in blood plasma. Biochem. Med. 1976; 15:212-215.